

US3742148 (Prod: University of Maryland School of Medicine)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:27:01

All time stamps listed in this document are displayed in GMT

US3742148

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 17:23:37

Generated On: 10 Jun 2021 09:27:01

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[Participant ID](#)

US3742148

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

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US3742148

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:21:17

Generated On: 10 Jun 2021 09:27:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 17:16:36

Generated On: 10 Jun 2021 09:27:01

Date of Birth (MMM yyyy)	(b) (6) 1996
Age	24
Age Units	YEARS
Age (Derived)	24
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 17:16:36

Generated On: 10 Jun 2021 09:27:01

Date of Informed Consent ( <i>dd MMM yyyy</i> )	28 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 17:16:36

Generated On: 10 Jun 2021 09:27:01

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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 17:16:36

Generated On: 10 Jun 2021 09:27:01

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 17:16:36

Generated On: 10 Jun 2021 09:27:01

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 17:16:36

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Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 17:16:36

Generated On: 10 Jun 2021 09:27:01

Condition	POST TRAUMATIC STRESS DISORDER
Start date (dd MMM yyyy)	UN NOV 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)	NOV 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:21:17

Generated On: 10 Jun 2021 09:27:01

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	28 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	16:43 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 16:43
Height ( <i>xxx.x</i> )	67.0 in
Weight ( <i>xxx.x</i> )	130.0 lb
BMI ( <i>xxx.x</i> )	20.40345 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:16:36

Generated On: 10 Jun 2021 09:27:01

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Was the physical examination performed?

Yes ☒

No ☐

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Date of examination (dd MMM yyyy)

28 AUG 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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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 17:16:36

Generated On: 10 Jun 2021 09:27:01

Date of assessment (*dd MMM yyyy*) 28 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 17:21:17

Generated On: 10 Jun 2021 09:27:01

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	28 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)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:21:17

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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**

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

**No Risk Identified** True

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:21:17

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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 17:21:17

Generated On: 10 Jun 2021 09:27:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 17:21:17

Generated On: 10 Jun 2021 09:27:01

What was the date of randomization? (dd MMM yyyy) 28 AUG 2020

What was the participant's randomization number? 109761

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 17:21:17

Generated On: 10 Jun 2021 09:27:01

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:21:17

Generated On: 10 Jun 2021 09:27:01

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)	28 AUG 2020
Time of assessment (00:00-23:59)	16:43 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 16:43
Temperature (xxx.x)	097.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	080 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	094 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	065 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:21:17

Generated On: 10 Jun 2021 09:27:01

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)	28 AUG 2020
Time of assessment (00:00-23:59)	17:43 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 17:43
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	087 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	101 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:21:17

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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 17:21:17

Generated On: 10 Jun 2021 09:27:01

Was the pregnancy test performed? Yes ☐  
No ☒

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

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☒

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

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

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:21:17

Generated On: 10 Jun 2021 09:27:01

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) 28 AUG 2020

What was the treatment time? (00:00-23:59) 17:13 (24 HR)

Treatment Date and Time (derived) 28 AUG 2020 17:13

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

What was the frequency of the study treatment dosing? ONCE

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



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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:21:17

Generated On: 10 Jun 2021 09:27:01

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 AUG 2020
Collection time (00:00-23:59)	16:36 (24 HR)
Collection date and time (derived)	28 AUG 2020 16:36

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:21:17

Generated On: 10 Jun 2021 09:27:01

Collection date (dd MMM yyyy)			28 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:40	28 AUG 2020 16:40
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:21:17

Generated On: 10 Jun 2021 09:27:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

28 AUG 2020 17:46

PC Open Date & Time

28 AUG 2020 17:33

PC Close Date & Time

28 AUG 2020 20:03

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

99.5 °F

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

Yes ☐  
No ☒

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

PC Time Stamp	29 AUG 2020 00:01
PC Open Date & Time	28 AUG 2020 20:58
PC Close Date & Time	29 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:27:01

**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

100.1 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

True

PC Time Stamp

30 AUG 2020 00:00

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:27:01

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.9 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	31 AUG 2020 08:42
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:27:01

**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

98.4 °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

01 SEP 2020 00:27

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59



US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

02 SEP 2020 09:50

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 01:07

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

04 SEP 2020 00:57

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

**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

28 AUG 2020 17:47

PC Open Date & Time

28 AUG 2020 17:33

PC Close Date & Time

28 AUG 2020 20:03

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

**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

28 AUG 2020 22:21

PC Open Date & Time

28 AUG 2020 20:58

PC Close Date & Time

29 AUG 2020 11:59

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:27:01

**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

29 AUG 2020 21:43

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:27:01

**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

31 AUG 2020 08:42

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:27:01

**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

01 SEP 2020 00:17

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59



US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:27:01

**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

02 SEP 2020 09:50

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:27:01

**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

03 SEP 2020 01:08

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:27:01

**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

04 SEP 2020 00:56

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

**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 ☐

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 17:48
PC Open Date & Time	28 AUG 2020 17:33
PC Close Date & Time	28 AUG 2020 20:03

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

**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 ☐

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 22:22
PC Open Date & Time	28 AUG 2020 20:58
PC Close Date & Time	29 AUG 2020 11:59

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:27:01

**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 ☒



US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:27:01

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 21:44
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:27:01

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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49 of 1822

EAB) (1725)

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:27:01

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 08:41
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:27:01

**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 ☒

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:27:01

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 00:17
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:27:01

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

53 of 1822

EAB) (1725)

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:27:01

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 09:50
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:27:01

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  
EAB) (1725)

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US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:27:01

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 01:08
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:27:01

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 ☒

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:27:01

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 00:56
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3742148

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:16:36

Generated On: 10 Jun 2021 09:27:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742148

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:16:36

Generated On: 10 Jun 2021 09:27:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742148

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:16:36

Generated On: 10 Jun 2021 09:27:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742148

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:16:36

Generated On: 10 Jun 2021 09:27:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742148

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:23:38

Generated On: 10 Jun 2021 09:27:01

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*



US3742148

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:23:38

Generated On: 10 Jun 2021 09:27:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742148

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:21:17

Generated On: 10 Jun 2021 09:27:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 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

US3742148

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:21:17

Generated On: 10 Jun 2021 09:27:01

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 SEP 2020
Time of assessment (00:00-23:59)	15:31 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 15:31
Temperature (xxx.x)	098.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	092 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	069 mmHg
Diastolic Blood Pressure units	MMHG

US3742148

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:21:17

Generated On: 10 Jun 2021 09:27:01

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 SEP 2020
Time of assessment (00:00-23:59)	16:52 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 16:52
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	080 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	070 mmHg
Diastolic Blood Pressure units	MMHG

US3742148

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:21:17

Generated On: 10 Jun 2021 09:27:01

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 SEP 2020

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

US3742148

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 15 Feb 2021 17:21:17

Generated On: 10 Jun 2021 09:27:01

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

US3742148

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:21:17

Generated On: 10 Jun 2021 09:27:01

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 16:22 (24 HR)

Treatment Date and Time (derived) 25 SEP 2020 16:22

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

What was the frequency of the study treatment dosing? ONCE

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

US3742148

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:21:17

Generated On: 10 Jun 2021 09:27:01

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 SEP 2020

Collection time (00:00-23:59)

15:50 (24 HR)

Collection date and time (derived)

25 SEP 2020 15:50



US3742148

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:21:17

Generated On: 10 Jun 2021 09:27:01

Collection date (dd MMM yyyy)			25 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:49	25 SEP 2020 15:49
Nasopharyngeal Swab 2	No		

US3742148

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:21:17

Generated On: 10 Jun 2021 09:27:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 16:58

PC Open Date & Time

25 SEP 2020 16:42

PC Close Date & Time

25 SEP 2020 19:12

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 99.2 °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	25 SEP 2020 21:32
PC Open Date & Time	25 SEP 2020 20:07
PC Close Date & Time	26 SEP 2020 11:59

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 01:23

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

28 SEP 2020 11:06

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 00:21

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

29 SEP 2020 22:37

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59



US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

30 SEP 2020 23:11

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:27:01

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 16:59

PC Open Date & Time

25 SEP 2020 16:42

PC Close Date & Time

25 SEP 2020 19:12

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 21:27

PC Open Date & Time

25 SEP 2020 20:07

PC Close Date & Time

26 SEP 2020 11:59

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

26 SEP 2020 22:57

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:27:01

**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

28 SEP 2020 11:07

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:27:01

**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

29 SEP 2020 00:17

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 22:33

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59



US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:27:01

**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

30 SEP 2020 23:12

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:27:01

**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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the  
ruler provided.

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

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE  
(in mm)**

Measure the largest size across any injection site swelling/hardness  
with the ruler provided.

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

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

**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 ☐

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

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

No ☒

Yes ☐

PC Time stamp	25 SEP 2020 17:00
PC Open Date & Time	25 SEP 2020 16:42
PC Close Date & Time	25 SEP 2020 19:12

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

**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 ☐

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

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

No ☒

Yes ☐

PC Time stamp	25 SEP 2020 21:28
PC Open Date & Time	25 SEP 2020 20:07
PC Close Date & Time	26 SEP 2020 11:59

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:27:01

**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 ☒

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:27:01

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 22:54
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59



US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:27:01

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

96 of 1822

EAB) (1725)

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:27:01

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 11:07
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:27:01

**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

98 of 1822

EAB) (1725)

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:27:01

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 00:17
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:27:01

**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)

100 of 1822

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:27:01

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 22:34
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:27:01

**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 ☒

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:27:01

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 23:11
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59



US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:27:01

**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 ☐

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:27:01

Yes ☐

PC Time stamp

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3742148

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:16:36

Generated On: 10 Jun 2021 09:27:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742148

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:16:36

Generated On: 10 Jun 2021 09:27:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742148

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:16:36

Generated On: 10 Jun 2021 09:27:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742148

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:16:36

Generated On: 10 Jun 2021 09:27:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742148

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:16:36

Generated On: 10 Jun 2021 09:27:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742148

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:16:36

Generated On: 10 Jun 2021 09:27:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3742148

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:21:17

Generated On: 10 Jun 2021 09:27:01

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

US3742148

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:21:17

Generated On: 10 Jun 2021 09:27:01

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) \_\_\_\_\_

US3742148

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:21:17

Generated On: 10 Jun 2021 09:27:01

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 OCT 2020

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

US3742148

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:21:17

Generated On: 10 Jun 2021 09:27:01

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 OCT 2020

Collection time (00:00-23:59)

15:21 (24 HR)

Collection date and time (derived)

23 OCT 2020 15:21

US3742148

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:21:17

Generated On: 10 Jun 2021 09:27:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742148

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	28 OCT 2020 19:59:27
Patient Cloud Open Date & Time	28 OCT 2020 00:01
Patient Cloud Close Date & Time	01 NOV 2020 23:59

US3742148

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**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

06 NOV 2020 12:44:12

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3742148

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 NOV 2020 07:09:38

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59



US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 NOV 2020 10:28:15

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 DEC 2020 22:20:08
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 DEC 2020 15:36:51

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 DEC 2020 00:02:55
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**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

21 DEC 2020 11:46:09

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 00:04:25

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**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

03 JAN 2021 13:03:19

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**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

11 JAN 2021 21:36:03

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59



US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	17 JAN 2021 09:55:26
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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 <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	28 JAN 2021 12:05:52
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	31 JAN 2021 00:03:50
Patient Cloud Open Date & Time	31 JAN 2021 00:01
Patient Cloud Close Date & Time	04 FEB 2021 23:59

US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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 <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	10 FEB 2021 20:03:15
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 FEB 2021 10:41:44
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**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

22 FEB 2021 05:39:43

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

<b>TIMEPOINT</b>	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 MAR 2021 19:40:54
Patient Cloud Open Date & Time	28 FEB 2021 00:01
Patient Cloud Close Date & Time	04 MAR 2021 23:59

US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 00:19:21

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59



US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**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

16 MAR 2021 16:49:08

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**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

23 MAR 2021 05:54:27

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**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

28 MAR 2021 05:25:53

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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 <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"/>

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

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[Patient Cloud Close Date & Time](#)

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08 APR 2021 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 05:28:37

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**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

20 APR 2021 21:27:38

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 06:09:00

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59



US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAY 2021 18:48:01

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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 <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"/>

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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09 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 MAY 2021 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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"/>

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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16 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAY 2021 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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"/>

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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23 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAY 2021 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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 <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"/>



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

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[Patient Cloud Close Date & Time](#)

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03 JUN 2021 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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"/>

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	06 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 JUN 2021 23:59

US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	13 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 JUN 2021 23:59

US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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"/>

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 JUN 2021 23:59

US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

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[Patient Cloud Close Date & Time](#)

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01 JUL 2021 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**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 ☐

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

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[Patient Cloud Close Date & Time](#)

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08 JUL 2021 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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"/>

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	11 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 JUL 2021 23:59

US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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"/>

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	18 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 JUL 2021 23:59

US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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"/>



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	25 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 JUL 2021 23:59

US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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"/>

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

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[Patient Cloud Close Date & Time](#)

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05 AUG 2021 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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="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"/>

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

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[Patient Cloud Close Date & Time](#)

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12 AUG 2021 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**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 ☐

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

15 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 AUG 2021 23:59

US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

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[Patient Cloud Close Date & Time](#)

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02 SEP 2021 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**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 ☐

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

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[Patient Cloud Close Date & Time](#)

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09 SEP 2021 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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"/>

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

12 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**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 ☐



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

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[Patient Cloud Close Date & Time](#)

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23 SEP 2021 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**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 ☐

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	26 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 SEP 2021 23:59

US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	03 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 OCT 2021 23:59

US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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"/>

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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10 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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14 OCT 2021 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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="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"/>



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 OCT 2021 23:59

US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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"/>

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 OCT 2021 23:59

US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**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 ☐

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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31 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 NOV 2021 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

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[Patient Cloud Close Date & Time](#)

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11 NOV 2021 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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"/>



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

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[Patient Cloud Close Date & Time](#)

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18 NOV 2021 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

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

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

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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21 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 NOV 2021 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

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[Patient Cloud Close Date & Time](#)

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02 DEC 2021 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**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 ☐  
Yes ☐

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

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

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[Patient Cloud Close Date & Time](#)

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09 DEC 2021 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

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

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



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	12 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 DEC 2021 23:59

US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	19 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	23 DEC 2021 23:59

US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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"/>

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

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[Patient Cloud Close Date & Time](#)

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30 DEC 2021 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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"/>

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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02 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 JAN 2022 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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"/>



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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09 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 JAN 2022 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**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 ☐

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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16 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 JAN 2022 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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23 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 JAN 2022 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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 <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"/>

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

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[Patient Cloud Close Date & Time](#)

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03 FEB 2022 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

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[Patient Cloud Close Date & Time](#)

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10 FEB 2022 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

TIMEPOINT	DAY 537
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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13 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 FEB 2022 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

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[Patient Cloud Close Date & Time](#)

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24 FEB 2022 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**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 ☐

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

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[Patient Cloud Close Date & Time](#)

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03 MAR 2022 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

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[Patient Cloud Close Date & Time](#)

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10 MAR 2022 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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 <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"/>

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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13 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAR 2022 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**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 ☐

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	20 MAR 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 MAR 2022 23:59
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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**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 ☐

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

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[Patient Cloud Close Date & Time](#)

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31 MAR 2022 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**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 ☐



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

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[Patient Cloud Close Date & Time](#)

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07 APR 2022 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

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

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

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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10 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 APR 2022 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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"/>

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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17 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 APR 2022 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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"/>

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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24 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 APR 2022 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

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[Patient Cloud Close Date & Time](#)

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05 MAY 2022 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

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[Patient Cloud Close Date & Time](#)

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12 MAY 2022 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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="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"/>

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

15 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

22 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

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[Patient Cloud Close Date & Time](#)

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02 JUN 2022 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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"/>

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

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[Patient Cloud Close Date & Time](#)

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09 JUN 2022 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	12 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 JUN 2022 23:59

US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**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 ☐

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

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[Patient Cloud Close Date & Time](#)

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23 JUN 2022 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

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[Patient Cloud Close Date & Time](#)

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30 JUN 2022 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**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 ☐

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

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[Patient Cloud Close Date & Time](#)

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07 JUL 2022 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 JUL 2022 23:59

US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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"/>

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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17 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 JUL 2022 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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24 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 JUL 2022 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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31 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 AUG 2022 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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"/>

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	07 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 AUG 2022 23:59

US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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"/>

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

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[Patient Cloud Close Date & Time](#)

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18 AUG 2022 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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"/>



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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21 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 AUG 2022 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

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[Patient Cloud Close Date & Time](#)

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01 SEP 2022 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

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[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	11 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 SEP 2022 23:59

US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

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[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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"/>

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

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[Patient Cloud Close Date & Time](#)

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29 SEP 2022 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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"/>

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

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[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

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[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 OCT 2022 23:59

US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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"/>

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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23 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 OCT 2022 23:59

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US3742148

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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"/>

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

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

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[Patient Cloud Close Date & Time](#)

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03 NOV 2022 23:59

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US3742148

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:27:01

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		01 MAR 2021 19:40:42

US3742148

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:23:38

Generated On: 10 Jun 2021 09:27:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742148

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:23:38

Generated On: 10 Jun 2021 09:27:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3742148

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:23:38

Generated On: 10 Jun 2021 09:27:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742148

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:23:38

Generated On: 10 Jun 2021 09:27:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742148

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 17:23:38

Generated On: 10 Jun 2021 09:27:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742148

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 17:23:38

Generated On: 10 Jun 2021 09:27:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742148

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:08:10

Generated On: 10 Jun 2021 09:27:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742148

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:08:10

Generated On: 10 Jun 2021 09:27:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742148

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 07 Apr 2021 21:08:10

Generated On: 10 Jun 2021 09:27:01

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 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

US3742148

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 21:08:10

Generated On: 10 Jun 2021 09:27:01

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) \_\_\_\_\_



US3742148

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 07 Apr 2021 21:08:10

Generated On: 10 Jun 2021 09:27:01

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.*

US3742148

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 07 Apr 2021 21:08:10

Generated On: 10 Jun 2021 09:27:01

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 MAR 2021

Collection time (00:00-23:59)

15:05 (24 HR)

Collection date and time (derived)

19 MAR 2021 15:05

US3742148

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:08:10

Generated On: 10 Jun 2021 09:27:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3742148

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 23 Apr 2021 17:54:39

Generated On: 10 Jun 2021 09:27:01

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3742148

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 17:54:38

Generated On: 10 Jun 2021 09:27:01

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3742148**

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

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:27:01**

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*

**US3742148**

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

**Form: Continuing**

**Generated On: 10 Jun 2021 09:27:01**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3742148

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:27:01

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



**US3742148**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 10 Jun 2021 09:27:01**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3742148

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 17:23:38

Generated On: 10 Jun 2021 09:27:01

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

Visit date (dd MMM yyyy)	27 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3742148

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

Form: Unblinding

Data signed: (b) (4) 13 Apr 2021 21:39:34

Generated On: 10 Jun 2021 09:27:01

Date of updated informed consent (dd MMM yyyy) 27 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☐ No ☒

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy)

Participant randomization assignment mRNA-1273 ☐ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☐

Placebo Only Flag

Continuing with mRNA-1273

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 17:23:38

Generated On: 10 Jun 2021 09:27:01

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 JAN 2021

Collection time (00:00-23:59)

09:23 (24 HR)

Collection date and time (derived)

27 JAN 2021 09:23

US3742148

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 17:23:38

Generated On: 10 Jun 2021 09:27:01

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 JAN 2021

Collection time (00:00 - 23:59)

09:27

Collection Date and Time (derived)

27 JAN 2021 09:27

US3742148

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 17:23:37

Generated On: 10 Jun 2021 09:27:01

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3742148

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 25 Mar 2021 17:56:37

Generated On: 10 Jun 2021 09:27:01

AEID	USA-US127-2021-MRNA-1273-P30 1000010
Adverse event	SPONTANEOUS ABORTION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	29 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	29 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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 (1)

Data signed: (b) (4) 25 Mar 2021 17:56:37

Generated On: 10 Jun 2021 09:27:01

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	



US3742148

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 25 Mar 2021 17:56:37

Generated On: 10 Jun 2021 09:27:01

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DAY 159 ALERT FOLLOW-UP  
YIELDED THAT THE  
VOLUNTEER HAD A  
MISCARRIAGE ON 29JAN2021. IT  
WAS CONFIRMED WITH HER  
OB/GYN ON 29JAN2021.  
PARTICIPANT REPORTED SHE  
WAS 6 WEEKS PREGNANT.

---

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)	

---

---

US3742148

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 25 Mar 2021 17:56:37

Generated On: 10 Jun 2021 09:27:01

AEID

Adverse event

URINARY TRACT 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)

21 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

28 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 25 Mar 2021 17:56:37

Generated On: 10 Jun 2021 09:27:01

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)	_____

US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 07 Apr 2021 21:08:09

Generated On: 10 Jun 2021 09:27:01

---

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

Yes ☒

No ☐

---

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

---

US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 07 Apr 2021 21:08:09

Generated On: 10 Jun 2021 09:27:01

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 07 Apr 2021 21:08:09

Generated On: 10 Jun 2021 09:27:01

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	30 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	01 SEP 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 07 Apr 2021 21:08:09

Generated On: 10 Jun 2021 09:27:01

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication FLU PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 07 Apr 2021 21:08:09

Generated On: 10 Jun 2021 09:27:01

	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)		20 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		20 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 07 Apr 2021 21:08:09

Generated On: 10 Jun 2021 09:27:01

Name of Medication NITROFUANTOIN

Prophylaxis Yes ☐  
No ☒

Indication URINARY TRACT 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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 07 Apr 2021 21:08:09

Generated On: 10 Jun 2021 09:27:01

	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)	21 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 07 Apr 2021 21:08:09

Generated On: 10 Jun 2021 09:27:01

Name of Medication PRAZOSIN

Prophylaxis Yes ☐  
No ☒

Indication POST TRAUMATIC STRESS  
DISORDER

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 07 Apr 2021 21:08:09

Generated On: 10 Jun 2021 09:27:01

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

US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 07 Apr 2021 21:08:09

Generated On: 10 Jun 2021 09:27:01

Name of Medication ESCITALOPRAM

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

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 ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 07 Apr 2021 21:08:09

Generated On: 10 Jun 2021 09:27:01

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

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 07 Apr 2021 21:08:09

Generated On: 10 Jun 2021 09:27:01

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:27:01

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



US3742148

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:27:01

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 ☐

US3742148

Folder: SAE USA-US127-2021-MRNA-1273-P301000010

Form: Safety Report Form

Data signed: (b) (4) 07 Apr 2021 21:08:10

Generated On: 10 Jun 2021 09:27:01

SAEID	USA-US127-2021-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3742148

Folder: SAE USA-US127-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Data signed: (b) (4) 07 Apr 2021 21:08:10

Generated On: 10 Jun 2021 09:27:01

SAEID	USA-US127-2021-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	04/FEB/2021 17:19
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

US3742148

Folder: SAE USA-US127-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Data signed: (b) (4) 07 Apr 2021 21:08:10

Generated On: 10 Jun 2021 09:27:01

SAEID	USA-US127-2021-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	KAREN
Investigator's Last Name	KOTLOFF
Site Address: Street	685 W. BALTIMORE STREET, HSF 480
Site Address: City	BALTIMORE
Site Address: State	
Site Address: Postal Code	21201
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	26/FEB/2021 12:03
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

US3742148 (Prod: University of Maryland School of Medicine)

**US3742148**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:27:01**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered 'US3742148'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 20:04:23

**US3742148**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:27:01**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:23:01

US3742148

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '28 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 20:04:25



US3742148

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:27:01

[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 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:23:01

**US3742148**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:27:01**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User entered 'SCRN'	System	28 Aug 2020 21:23:01

US3742148

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:27:01

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered (b) (6) 1996'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 20:04:26

**US3742148**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:27:01**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered '24'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:23:27

**US3742148**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:27:01**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User entered 'YEARS'	System	28 Aug 2020 21:23:27

**US3742148**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:27:01**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User entered '24'	System	28 Aug 2020 21:24:18

**US3742148**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:27:01**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:23:27

**US3742148**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:27:01**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:23:27



**US3742148**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:27:01**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:23:27

**US3742148**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:27:01**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered 'I'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:23:27

**US3742148**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:27:01**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:23:27

**US3742148**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:27:01**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:23:27

**US3742148**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:27:01**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:23:27

**US3742148**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:27:01**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:23:27

US3742148

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:27:01

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:23:27

**US3742148**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:27:01**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:23:27



**US3742148**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:27:01**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:23:27

US3742148

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:27:01

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered '28 Aug 2020'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:24:18

**US3742148**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User entered 'Aug 2020'	System	28 Aug 2020 21:24:18

**US3742148**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User entered '2020'	System	28 Aug 2020 21:24:18

**US3742148**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:27:01**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:24:18

US3742148

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:24:18

US3742148

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:27:01

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:24:18

**US3742148**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:27:01**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:24:18



**US3742148**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:27:01**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:24:18

US3742148

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:27:01

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 20:04:25

**US3742148**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:27:01**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User entered 'I'	System	28 Aug 2020 21:24:54

US3742148

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:24:54

US3742148

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:27:01

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered 'Yes (Y)'	Hassan Haji (b) (4)	31 Aug 2020 14:36:25

US3742148

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:27:01

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 14:41:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 14:41:42
Data point term sent to Coder	System	31 Aug 2020 14:39:46
User entered 'anxiety'	Hassan Haji (b) (4)	31 Aug 2020 14:39:39
	(b) (4)	

**US3742148**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered 'UN UNK 2016' reason for change:	(b) (4)	
Data Entry Error	Kaitlin Mason (b) (4)	11 Sep 2020 20:07:06
User entered '30 Jun 2016'	(b) (4)	
	Hassan Haji (b) (4)	31 Aug 2020 14:39:39
	(b) (4)	

**US3742148**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:27:01**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered '0'	Hassan Haji (b) (4)	31 Aug 2020 14:39:39



**US3742148**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:27:01**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered 'Yes (Y)'	Hassan Haji (b) (4)	31 Aug 2020 14:39:39

**US3742148**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered empty.	Hassan Haji (b) (4)	31 Aug 2020 14:39:39

**US3742148**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:27:01**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered '0'	Hassan Haji (b) (4)	31 Aug 2020 14:39:39

**US3742148**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User entered 'Jan 2016'	System	11 Sep 2020 20:07:06
User entered 'Jun 2016'	System	31 Aug 2020 14:39:39

**US3742148**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User entered '2016'	System	31 Aug 2020 14:39:39

**US3742148**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User entered empty.	System	31 Aug 2020 14:39:39

**US3742148**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User entered empty.	System	31 Aug 2020 14:39:39

US3742148

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:27:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
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)	31 Aug 2020 14:41:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 14:41:41
Data point term sent to Coder	System	31 Aug 2020 14:40:49
User entered 'depression'	Hassan Haji (b) (4)	31 Aug 2020 14:40:04



**US3742148**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered 'UN UNK 2016' reason for change:	(b) (4)	
Data Entry Error	Kaitlin Mason (b) (4)	11 Sep 2020 20:07:15
User entered '30 Jun 2016'	(b) (4)	
	Hassan Haji (b) (4)	31 Aug 2020 14:40:04
	(b) (4)	

US3742148

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:27:01

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered '0'	Hassan Haji (b) (4)	31 Aug 2020 14:40:04

**US3742148**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:27:01**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered 'Yes (Y)'	Hassan Haji (b) (4)	31 Aug 2020 14:40:04

**US3742148**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered empty.	Hassan Haji (b) (4)	31 Aug 2020 14:40:04

US3742148

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:27:01

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered '0'	Hassan Haji (b) (4)	31 Aug 2020 14:40:04

**US3742148**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User entered 'Jan 2016'	System	11 Sep 2020 20:07:15
User entered 'Jun 2016'	System	31 Aug 2020 14:40:04

**US3742148**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User entered '2016'	System	31 Aug 2020 14:40:04

**US3742148**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User entered empty.	System	31 Aug 2020 14:40:04



**US3742148**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User entered empty.	System	31 Aug 2020 14:40:04

US3742148

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:27:01

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Stress disorders, PT: Post-traumatic stress disorder, LLT: Post-traumatic stress disorder - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	31 Aug 2020 14:42:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 14:42:35
Data point term sent to Coder	System	31 Aug 2020 14:41:51
User entered 'post traumatic stress disorder'	Hassan Haji (b) (4)	31 Aug 2020 14:40:50
	(b) (4)	

**US3742148**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered 'UN Nov 2018' reason for change: Data Entry Error	Kaitlin Mason (b) (4)	11 Sep 2020 20:07:24
User entered '15 Nov 2018'	Hassan Haji (b) (4)	31 Aug 2020 14:40:50

**US3742148**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:27:01**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered '0'	Hassan Haji (b) (4)	31 Aug 2020 14:40:50

**US3742148**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:27:01**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered 'Yes (Y)'	Hassan Haji (b) (4)	31 Aug 2020 14:40:50

US3742148

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered empty.	Hassan Haji (b) (4)	31 Aug 2020 14:40:50

**US3742148**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:27:01**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered '0'	Hassan Haji (b) (4)	31 Aug 2020 14:40:50

**US3742148**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User entered 'Nov 2018'	System	31 Aug 2020 14:40:50



**US3742148**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User entered '2018'	System	31 Aug 2020 14:40:50

**US3742148**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User entered empty.	System	31 Aug 2020 14:40:50

**US3742148**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User entered empty.	System	31 Aug 2020 14:40:50

US3742148

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'Yes (Y)'	Hassan Haji (b) (4)	31 Aug 2020 14:37:48

US3742148

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '28 Aug 2020'	Hassan Haji (b) (4)	31 Aug 2020 14:37:48

US3742148

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '16:43'	Hassan Haji (b) (4)	31 Aug 2020 14:37:48

**US3742148**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User entered '28 Aug 2020 16:43'	System	31 Aug 2020 14:37:48

US3742148

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '67.0' in	(b) (4) Hassan Haji (b) (4)	31 Aug 2020 14:37:48
DataPoint set to visible.	(b) (4) System	28 Aug 2020 21:24:54



US3742148

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '130.0' lb	Hassan Haji (b) (4)	31 Aug 2020 14:37:48
DataPoint set to visible.	System	28 Aug 2020 21:24:54

US3742148

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User entered '20.40345'	System	31 Aug 2020 14:37:48
DataPoint set to visible.	System	28 Aug 2020 21:24:54

US3742148

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User entered 'kg/m2'	System	31 Aug 2020 14:37:48
DataPoint set to visible.	System	28 Aug 2020 21:24:54

US3742148

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
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)	22 Sep 2020 19:01:15
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 ERROR' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 19:07:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 19:07:42
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)	18 Sep 2020 20:38:16
User entered '097.4' F	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 14:37:48

US3742148

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4)	21 Sep 2020 19:07:42
User entered 'Oral (Oral)'	Hassan Haji (b) (4)	31 Aug 2020 14:37:48

US3742148

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered empty.	Hassan Haji (b) (4)	31 Aug 2020 14:37:48

US3742148

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 19:07:42
User entered '080'	Kaitlin Mason (b) (4)	31 Aug 2020 14:37:48
	Hassan Haji (b) (4)	
	(b) (4)	

**US3742148**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:27:01**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User entered 'bpm'	System	31 Aug 2020 14:37:48



US3742148

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 19:07:42
User entered '14'	Kaitlin Mason (b) (4)	31 Aug 2020 14:37:48
	Hassan Haji (b) (4)	
	(b) (4)	

US3742148

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User entered 'breaths/min'	System	31 Aug 2020 14:37:48

US3742148

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 19:07:42
User entered '094'	Kaitlin Mason (b) (4)	31 Aug 2020 14:37:48
	Hassan Haji (b) (4)	
	(b) (4)	

**US3742148**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:27:01**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User entered 'mmHg'	System	31 Aug 2020 14:37:48

US3742148

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Sep 2020 19:07:42
User entered '065'	Kaitlin Mason (b) (4)	31 Aug 2020 14:37:48
	Hassan Haji (b) (4)	
	(b) (4)	

**US3742148**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:27:01**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User entered 'mmHg'	System	31 Aug 2020 14:37:48

**US3742148**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:27:01**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11



US3742148

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:27:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered 'Yes (Y)'	Hassan Haji (b) (4)	31 Aug 2020 14:37:56

US3742148

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:27:01

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered '28 Aug 2020'	Hassan Haji (b) (4)	31 Aug 2020 14:37:56

US3742148

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:27:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered '28 Aug 2020'	Hassan Haji (b) (4)	31 Aug 2020 14:38:44

US3742148

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered 'Yes (Y)'	Hassan Haji (b) (4)	31 Aug 2020 14:38:44

US3742148

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered empty.	Hassan Haji (b) (4)	31 Aug 2020 14:38:44

US3742148

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:27:01

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered empty.	Hassan Haji (b) (4)	31 Aug 2020 14:38:44

US3742148

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered empty.	Hassan Haji (b) (4)	31 Aug 2020 14:38:44

**US3742148**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:27:01**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered '0'	Hassan Haji (b) (4)	31 Aug 2020 14:38:44



US3742148

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered empty.	Hassan Haji (b) (4)	31 Aug 2020 14:38:44

US3742148

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:27:01

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered '0'	Hassan Haji (b) (4)	31 Aug 2020 14:38:44

US3742148

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:27:01

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'Yes (Y)'	Hassan Haji (b) (4)	31 Aug 2020 14:41:23

US3742148

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:27:01

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '28 Aug 2020'	Hassan Haji (b) (4)	31 Aug 2020 14:41:23

**US3742148**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:27:01**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'Urine (URINE)'	Hassan Haji (b) (4)	31 Aug 2020 14:41:23

US3742148

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:27:01

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'Negative (NEGATIVE)'	Hassan Haji (b) (4)	31 Aug 2020 14:41:23

US3742148

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:27:01

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'No (N)'	Hassan Haji (b) (4)	31 Aug 2020 14:41:23

**US3742148**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:27:01**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered empty.	Hassan Haji (b) (4)	31 Aug 2020 14:41:23



**US3742148**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:27:01**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered empty.	Hassan Haji (b) (4)	31 Aug 2020 14:41:23

**US3742148**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User entered empty.	System	31 Aug 2020 14:41:23

US3742148

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:27:01

[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 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:25:30

US3742148

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:27:01

**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 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:25:30

US3742148

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:27:01

**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 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:25:30

US3742148

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:27:01

**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 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:25:30

US3742148

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:27:01

[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 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:25:30

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Folder: Screening

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:25:30



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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:25:30

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Folder: Screening

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:25:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:25:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:25:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:25:30

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:25:30

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:25:30

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Folder: Screening

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'I'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:25:30



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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:25:30

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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 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:25:30

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[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 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:25:30

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Folder: Screening

Form: Risk of Exposure

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**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 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:25:30

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:25:30

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:27:01

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:25:30

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:27:01

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:25:30

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:27:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'Yes (Y)'	Hassan Haji (b) (4)	31 Aug 2020 14:42:47



**US3742148**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '28 Aug 2020'	Hassan Haji (b) (4)	31 Aug 2020 14:42:47

US3742148

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:27:01

[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 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'Clinic (Clinic)'	Hassan Haji (b) (4)	31 Aug 2020 14:42:47

**US3742148**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:27:01**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered 'VISIT1'	System	31 Aug 2020 14:42:47

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '28 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 21:04:33

US3742148

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '109761'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 21:04:33

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 21:04:33

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Folder: Visit 1 Day 1

Form: Randomization

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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 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'No (N)'	Hassan Haji (b) (4)	31 Aug 2020 14:43:07

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Folder: Visit 1 Day 1

Form: Randomization

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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 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'No (N)'	Hassan Haji (b) (4)	31 Aug 2020 14:43:07



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Folder: Visit 1 Day 1

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'No (N)'	Hassan Haji (b) (4)	31 Aug 2020 14:43:07

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**Folder: Visit 1 Day 1**

**Form: Randomization**

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[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'No (N)'	Hassan Haji (b) (4)	31 Aug 2020 14:43:07

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Folder: Visit 1 Day 1

Form: Randomization

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[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'No (N)'	Hassan Haji (b) (4)	31 Aug 2020 14:43:07

**US3742148**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'No (N)'	Kaitlin Mason (b) (4)	21 Sep 2020 19:07:59
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:33:24
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:33:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:27:01

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
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)	22 Sep 2020 08:53:33
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 ERROR' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 19:08:14
User entered missing code ND - Not Done; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 19:08:10
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)	18 Sep 2020 20:38:23
User entered '67.0' in	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 14:44:35

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:27:01

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered missing code ND - Not Done; reason for change New Information	(b) (4)	
	Kaitlin Mason (b) (4)	21 Sep 2020 19:08:10
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
	System	31 Aug 2020 14:54:09
User entered '130.0' lb reason for change: New Information	Hassan Haji (b) (4)	31 Aug 2020 14:54:09
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Aug 2020 14:44:35
User entered '13' (non-conformant).	Hassan Haji (b) (4)	31 Aug 2020 14:44:35
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:27:01

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
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)	22 Sep 2020 08:53:33
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 ERROR' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 19:08:14
User entered missing code ND - Not Done; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 19:08:10
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)	18 Sep 2020 20:38:23
User entered '67.0' in	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 14:44:35

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

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Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered missing code ND - Not Done; reason for change New Information	(b) (4)	
	Kaitlin Mason (b) (4)	21 Sep 2020 19:08:10
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
	System	31 Aug 2020 14:54:09
User entered '130.0' lb reason for change: New Information	Hassan Haji (b) (4)	31 Aug 2020 14:54:09
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Aug 2020 14:44:35
User entered '13' (non-conformant).	Hassan Haji (b) (4)	31 Aug 2020 14:44:35
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User accepted default value 'Pre-Dose (PREDOSE)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 14:44:35

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:01

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
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	31 Aug 2020 14:54:09
User entered 'Yes (Y)' reason for change: New Information	Hassan Haji (b) (4)	31 Aug 2020 14:54:09
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	31 Aug 2020 14:44:35
	Hassan Haji (b) (4)	31 Aug 2020 14:44:35
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '28 Aug 2020' reason for change: New Information	(b) (4)	31 Aug 2020 14:54:09
User entered empty.	Hassan Haji (b) (4)	31 Aug 2020 14:44:35
	(b) (4)	

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Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '16:43' reason for change: New Information	Hassan Haji (b) (4)	31 Aug 2020 14:54:09
User entered empty.	Hassan Haji (b) (4)	31 Aug 2020 14:44:35

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Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered '28 Aug 2020 16:43'	System	31 Aug 2020 14:54:09
User entered empty.	System	31 Aug 2020 14:44:35

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '097.4' F reason for change: New Information	(b) (4) Hassan Haji (b) (4)	31 Aug 2020 14:54:09
User entered empty.	(b) (4) Hassan Haji (b) (4)	31 Aug 2020 14:44:35

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'Oral (Oral)' reason for change: New Information	Hassan Haji (b) (4)	31 Aug 2020 14:54:09
User entered empty.	Hassan Haji (b) (4)	31 Aug 2020 14:44:35

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	31 Aug 2020 14:44:35



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '080' reason for change: New Information	(b) (4) Hassan Haji (b) (4)	31 Aug 2020 14:54:09
User entered empty.	(b) (4) Hassan Haji (b) (4)	31 Aug 2020 14:44:35

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered 'bpm'	System	31 Aug 2020 14:54:09
User entered empty.	System	31 Aug 2020 14:44:35

US3742148

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '14' reason for change: Data Entry Error	(b) (4)	
	Hassan Haji (b) (4)	31 Aug 2020 14:54:09
User entered empty.	(b) (4)	
	Hassan Haji (b) (4)	31 Aug 2020 14:44:35
	(b) (4)	

US3742148

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered 'breaths/min'	System	31 Aug 2020 14:54:09
User entered empty.	System	31 Aug 2020 14:44:35

US3742148

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '094' reason for change: New Information	(b) (4) Hassan Haji (b) (4)	31 Aug 2020 14:54:09
User entered empty.	(b) (4) Hassan Haji (b) (4)	31 Aug 2020 14:44:35

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered 'mmHg'	System	31 Aug 2020 14:54:09
User entered empty.	System	31 Aug 2020 14:44:35

US3742148

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '065' reason for change: New Information	(b) (4) Hassan Haji (b) (4)	31 Aug 2020 14:54:09
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	31 Aug 2020 14:44:35

US3742148

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered 'mmHg'	System	31 Aug 2020 14:54:09
User entered empty.	System	31 Aug 2020 14:44:35



US3742148

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:27:01

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
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)	22 Sep 2020 08:53:33
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 ERROR' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 19:08:14
User entered missing code ND - Not Done; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 19:08:10
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)	18 Sep 2020 20:38:23
User entered '67.0' in	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 14:44:35

US3742148

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:27:01

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered missing code ND - Not Done; reason for change New Information	(b) (4)	
	Kaitlin Mason (b) (4)	21 Sep 2020 19:08:10
	(b) (4)	
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Aug 2020 14:54:09
User entered '130.0' lb reason for change: New Information	Hassan Haji (b) (4)	31 Aug 2020 14:54:09
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Aug 2020 14:44:35
User entered '13' (non-conformant).	Hassan Haji (b) (4)	31 Aug 2020 14:44:35
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User accepted default value 'Post-Dose (POSTDOSE)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 14:44:35

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:01

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
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	31 Aug 2020 14:54:09
User entered 'Yes (Y)' reason for change: New Information	Hassan Haji (b) (4)	31 Aug 2020 14:54:09
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	31 Aug 2020 14:44:35
	Hassan Haji (b) (4)	31 Aug 2020 14:44:35
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '28 Aug 2020' reason for change: New Information	(b) (4)	31 Aug 2020 14:54:09
User entered empty.	Hassan Haji (b) (4)	31 Aug 2020 14:44:35
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '17:43' reason for change: New Information	Hassan Haji (b) (4)	31 Aug 2020 14:54:09
User entered empty.	Hassan Haji (b) (4)	31 Aug 2020 14:44:35

**US3742148**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered '28 Aug 2020 17:43'	System	31 Aug 2020 14:54:09
User entered empty.	System	31 Aug 2020 14:44:35

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '97.1' F reason for change: New Information	Hassan Haji (b) (4)	31 Aug 2020 14:54:09
User entered empty.	Hassan Haji (b) (4)	31 Aug 2020 14:44:35



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'Other (Other)' reason for change: New Information	(b) (4)	31 Aug 2020 14:54:09
User entered empty.	Hassan Haji (b) (4)	31 Aug 2020 14:44:35
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'forehead' reason for change: Data Entry Error	(b) (4)	
	Hassan Haji (b) (4)	31 Aug 2020 14:54:09
User entered empty.	(b) (4)	
	Hassan Haji (b) (4)	31 Aug 2020 14:44:35
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '087' reason for change: New Information	(b) (4) Hassan Haji (b) (4)	31 Aug 2020 14:54:09
User entered empty.	(b) (4) Hassan Haji (b) (4)	31 Aug 2020 14:44:35

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered 'bpm'	System	31 Aug 2020 14:54:09
User entered empty.	System	31 Aug 2020 14:44:35

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '20' reason for change: Data Entry Error	(b) (4)	
	Hassan Haji (b) (4)	31 Aug 2020 14:54:09
User entered empty.	(b) (4)	
	Hassan Haji (b) (4)	31 Aug 2020 14:44:35
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered 'breaths/min'	System	31 Aug 2020 14:54:09
User entered empty.	System	31 Aug 2020 14:44:35

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '101' reason for change: New Information	Hassan Haji (b) (4)	31 Aug 2020 14:54:09
User entered empty.	Hassan Haji (b) (4)	31 Aug 2020 14:44:35

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered 'mmHg'	System	31 Aug 2020 14:54:09
User entered empty.	System	31 Aug 2020 14:44:35



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '67' reason for change: New Information	Hassan Haji (b) (4)	31 Aug 2020 14:54:09
User entered empty.	Hassan Haji (b) (4)	31 Aug 2020 14:44:35

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered 'mmHg'	System	31 Aug 2020 14:54:09
User entered empty.	System	31 Aug 2020 14:44:35

US3742148

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:27:01

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
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 19:06:59
Query 'Per CDM: To avoid duplication of data, the CCG page 15-16 states, If a participant is screened, enrolled, randomized, and dose on the same day then completion of the PE form is only required to be completed using the PE form located in the screening folder. Completion of the PE form within the Visit 1 Day 1 folder should be left blank except for the response to "Was the physical examination performed?" This should be "No". Please update accordingly.' answered with 'ENTERED IN ERROR UPDATED' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 16:36:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 16:36:03
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)	18 Sep 2020 20:38:32
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 14:54:18

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:27:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Sep 2020 16:36:03
User entered '28 Aug 2020'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 14:54:18

US3742148

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:27:01

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
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)	23 Sep 2020 13:18:50
Query 'per CDM: Subject was screened and dosed on the same day and duplicate data have been recorded on the Pregnancy Test forms at Screening and Visit 1 Day 1. Please consider updating 'Was the pregnancy test performed?' to No at Visit 1 Day 1, if a second test was not performed. Alternatively, please explain.' answered with 'ENTERED IN ERROR' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 19:08:34
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 19:08:30
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 18:00:36
User entered 'Yes (Y)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 14:55:10

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:27:01

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4)	21 Sep 2020 19:08:30
User entered '28 Aug 2020'	Hassan Haji (b) (4)	31 Aug 2020 14:55:10

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:27:01

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4)	21 Sep 2020 19:08:30
User entered 'Urine (URINE)'	Hassan Haji (b) (4)	31 Aug 2020 14:55:10

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:27:01

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4)	21 Sep 2020 19:08:30
User entered 'Negative (NEGATIVE)'	Hassan Haji (b) (4)	31 Aug 2020 14:55:10



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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:27:01

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
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 14:57:18
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 13:24:18
User entered 'No (N)' reason for change: Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	12 Oct 2020 13:24:15
User opened query 'per CDM: please input yes or no in this field' (Site from DM).	(b) (4), (b) (6)	11 Oct 2020 14:18:06
User entered empty; reason for change Data Entry Error	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 19:08:30
User entered 'No (N)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 14:55:10

**US3742148**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:27:01**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered empty.	Hassan Haji (b) (4)	31 Aug 2020 14:55:10

US3742148

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:27:01

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered empty.	Hassan Haji (b) (4)	31 Aug 2020 14:55:10

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**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered empty.	System	31 Aug 2020 14:55:10

US3742148

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:27:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:27:18

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:27:01

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:27:18

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:27:01

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 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:27:18

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:27:01

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 21:27:18



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:27:01

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '28 Aug 2020'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:27:18

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:27:01

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '17:13'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:27:18

US3742148

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:27:01

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered '28 Aug 2020 17:13'	System	28 Aug 2020 21:27:18

US3742148

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:27:01

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 21:27:18

US3742148

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:27:01

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered 'ONCE'	System	28 Aug 2020 21:27:18

US3742148

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:27:01

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 21:27:18

US3742148

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:27:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'Yes (Y)'	Hassan Haji (b) (4)	31 Aug 2020 14:41:50

US3742148

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:27:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '28 Aug 2020'	Hassan Haji (b) (4)	31 Aug 2020 14:41:50



US3742148

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:27:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '16:36'	Hassan Haji (b) (4)	31 Aug 2020 14:41:50

**US3742148**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered '28 Aug 2020 16:36'	System	31 Aug 2020 14:41:50

US3742148

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:27:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '28 Aug 2020'	Hassan Haji (b) (4)	31 Aug 2020 14:42:08

**US3742148**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:27:01**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 14:42:08

US3742148

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:27:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'Yes (Y)'	Hassan Haji (b) (4)	31 Aug 2020 14:42:08

**US3742148**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:27:01**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '16:40'	Hassan Haji (b) (4)	31 Aug 2020 14:42:08

**US3742148**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered '28 Aug 2020 16:40'	System	31 Aug 2020 14:42:08

**US3742148**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:27:01**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Hassan Haji (b) (4) (b) (4)	31 Aug 2020 14:42:08



US3742148

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:27:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'No (N)'	Hassan Haji (b) (4)	31 Aug 2020 14:42:08

US3742148

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:27:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered empty.	Hassan Haji (b) (4)	31 Aug 2020 14:42:08

**US3742148**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered empty.	System	31 Aug 2020 14:42:08

US3742148

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:27:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'Yes (Y)'	Hassan Haji (b) (4)	31 Aug 2020 14:55:25

**US3742148**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:27:01**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered 'I'	System	31 Aug 2020 14:55:25

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	28 Aug 2020 21:27:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-28T17:46:09', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '64731a68-aa03-472b-b1e8-fab742d4e0f3'	System	28 Aug 2020 21:46:37
User entered 'Yes (Y)'	System	28 Aug 2020 21:46:37

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-28T17:46:22', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '64731a68-aa03-472b-b1e8-fab742d4e0f3'	System	28 Aug 2020 21:46:37
User entered '97.1'	System	28 Aug 2020 21:46:37



US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-28T17:46:28', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '64731a68-aa03-472b-b1e8-fab742d4e0f3'	System	28 Aug 2020 21:46:37
User entered 'No (N)'	System	28 Aug 2020 21:46:37

**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-28T17:46:31', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '64731a68-aa03-472b-b1e8-fab742d4e0f3'	System	28 Aug 2020 21:46:37
User entered '28 Aug 2020 17:46'	System	28 Aug 2020 21:46:37

**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '28 Aug 2020 17:33'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '28 Aug 2020 20:03'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	28 Aug 2020 21:27:18
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-29T00:01:09', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5b377ec4-a3da-404c-b2b0-4a2317901c71'	System	29 Aug 2020 04:01:30
User entered 'Yes (Y)'	System	29 Aug 2020 04:01:30

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-29T00:01:12', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5b377ec4-a3da-404c-b2b0-4a2317901c71' User entered '99.5'	System	29 Aug 2020 04:01:30
	System	29 Aug 2020 04:01:30

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-29T00:01:17', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5b377ec4-a3da-404c-b2b0-4a2317901c71'	System	29 Aug 2020 04:01:30
User entered 'No (N)'	System	29 Aug 2020 04:01:30



**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-29T00:01:22', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5b377ec4-a3da-404c-b2b0-4a2317901c71'	System	29 Aug 2020 04:01:30
User entered '29 Aug 2020 00:01'	System	29 Aug 2020 04:01:30

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '28 Aug 2020 20:58'	System	28 Aug 2020 21:27:18

**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	28 Aug 2020 21:27:18
User entered 'Day 2'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:27:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-29T23:59:40', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '358823a9-84cb-42e0-adbc-4bff6a0ea2fd'	System	30 Aug 2020 04:00:27
User entered 'Yes (Y)'	System	30 Aug 2020 04:00:27

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:27:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-29T23:59:54', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '358823a9-84cb-42e0-adbc-4bff6a0ea2fd'	System	30 Aug 2020 04:00:27
User entered '100.1'	System	30 Aug 2020 04:00:27

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-29T23:59:58', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '358823a9-84cb-42e0-adbc-4bff6a0ea2fd'	System	30 Aug 2020 04:00:27
User entered 'Yes (Y)'	System	30 Aug 2020 04:00:27

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User closed query 'Per CDM: Response is noted, however, no ConMed is recorded in Concomitant Medication and Vaccination Form. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 13:11:54
Query 'Per CDM: Response is noted, however, no ConMed is recorded in Concomitant Medication and Vaccination Form. Please review and reconcile. ' answered with 'CONMEDS UPDATED' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 19:11:04
User opened query 'Per CDM: Response is noted, however, no ConMed is recorded in Concomitant Medication and Vaccination Form. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	07 Sep 2020 15:13:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 15:10:40
Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Participant contacted. Tylenol 325mg taken to treat fever and injection site pain' (Site from System).	Faith Pa'ahana-Brown (b) (4)	04 Sep 2020 20:33:30
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	30 Aug 2020 04:00:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-30T00:00:19', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '358823a9-84cb-42e0-adbc-4bffa0ea2fd'	System	30 Aug 2020 04:00:27
User entered '1'	System	30 Aug 2020 04:00:27



US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:27:01

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Participant contacted. Tylenol 325mg taken to treat injection site pain' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 15:10:43
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Faith Pa'ahana-Brown	04 Sep 2020 20:33:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-30T00:00:19', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '358823a9-84cb-42e0-adbc-4bff6a0ea2fd'	(b) (4)	
User entered '1'	System	30 Aug 2020 04:00:27
	System	30 Aug 2020 04:00:27
	System	30 Aug 2020 04:00:27

**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-30T00:00:22', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '358823a9-84cb-42e0-adbc-4bff6a0ea2fd'	System	30 Aug 2020 04:00:27
User entered '30 Aug 2020 00:00'	System	30 Aug 2020 04:00:27

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:27:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 21:27:18

**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	28 Aug 2020 21:27:18
User entered 'Day 3'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:27:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-31T08:42:12', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'a4b287a8-d792-4554-baed-9634dbfeb6c6'	System	31 Aug 2020 12:42:42
User entered 'Yes (Y)'	System	31 Aug 2020 12:42:42

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:27:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-31T08:42:19', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'a4b287a8-d792-4554-baed-9634dbfeb6c6'	System	31 Aug 2020 12:42:42
User entered '98.9'	System	31 Aug 2020 12:42:42

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-31T08:42:25', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'a4b287a8-d792-4554-baed-9634dbfeb6c6'	System	31 Aug 2020 12:42:42
User entered 'Yes (Y)'	System	31 Aug 2020 12:42:42



US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Participant contacted. Tylenol 325 mg to treat injection site pain' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 15:09:58
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Faith Pa'ahana-Brown	04 Sep 2020 22:14:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-31T08:42:32', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'a4b287a8-d792-4554-baed-9634dbfeb6c6'	(b) (4)	
User entered '1'	System	31 Aug 2020 12:42:42
	System	31 Aug 2020 12:42:42
	System	31 Aug 2020 12:42:42

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:27:01

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-31T08:42:32', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'a4b287a8-d792-4554-baed-9634dbfeb6c6' User entered '0'	System	31 Aug 2020 12:42:42
	System	31 Aug 2020 12:42:42

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:27:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-31T08:42:35', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'a4b287a8-d792-4554-baed-9634dbfeb6c6'	System	31 Aug 2020 12:42:42
User entered '31 Aug 2020 08:42'	System	31 Aug 2020 12:42:42

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:27:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:27:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	28 Aug 2020 21:27:18
User entered 'Day 4'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:27:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-01T00:27:39', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '4914eae9-9da4-48ef-8da6-53a511a83022'	System	01 Sep 2020 04:28:03
User entered 'Yes (Y)'	System	01 Sep 2020 04:28:03

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:27:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-01T00:27:44', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '4914eae9-9da4-48ef-8da6-53a511a83022'	System	01 Sep 2020 04:28:03
User entered '98.4'	System	01 Sep 2020 04:28:03



US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-01T00:27:54', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '4914eae9-9da4-48ef-8da6-53a511a83022'	System	01 Sep 2020 04:28:03
User entered 'No (N)'	System	01 Sep 2020 04:28:03

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:27:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-01T00:27:57', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '4914eae9-9da4-48ef-8da6-53a511a83022'	System	01 Sep 2020 04:28:03
User entered '01 Sep 2020 00:27'	System	01 Sep 2020 04:28:03

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:27:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 21:27:18

**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	28 Aug 2020 21:27:18
User entered 'Day 5'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:27:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-02T09:49:45', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'c15f6035-7b08-4d05-bd9a-5430f1836383'	System	02 Sep 2020 13:50:11
User entered 'Yes (Y)'	System	02 Sep 2020 13:50:11

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:27:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-02T09:49:58', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'c15f6035-7b08-4d05-bd9a-5430f1836383'	System	02 Sep 2020 13:50:11
User entered '98.2'	System	02 Sep 2020 13:50:11

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-02T09:50:04', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'c15f6035-7b08-4d05-bd9a-5430f1836383'	System	02 Sep 2020 13:50:11
User entered 'No (N)'	System	02 Sep 2020 13:50:11



US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:27:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-02T09:50:07', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'c15f6035-7b08-4d05-bd9a-5430f1836383'	System	02 Sep 2020 13:50:11
User entered '02 Sep 2020 09:50'	System	02 Sep 2020 13:50:11

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:27:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 21:27:18

**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	28 Aug 2020 21:27:18
User entered 'Day 6'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:27:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-03T01:07:19', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '8a5fed61-1684-441e-a0c5-d91e35e274f1'	System	03 Sep 2020 05:08:00
User entered 'Yes (Y)'	System	03 Sep 2020 05:08:00

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:27:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-03T01:07:24', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '8a5fed61-1684-441e-a0c5-d91e35e274f1' User entered '99.0'	System	03 Sep 2020 05:08:00
	System	03 Sep 2020 05:08:00

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-03T01:07:51', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '8a5fed61-1684-441e-a0c5-d91e35e274f1'	System	03 Sep 2020 05:08:00
User entered 'No (N)'	System	03 Sep 2020 05:08:00

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:27:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-03T01:07:55', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '8a5fed61-1684-441e-a0c5-d91e35e274f1'	System	03 Sep 2020 05:08:00
User entered '03 Sep 2020 01:07'	System	03 Sep 2020 05:08:00



**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:27:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	28 Aug 2020 21:27:18
User entered 'Day 7'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:27:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-04T00:56:43', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'b66334ef-7235-4c90-b482-21ef7651ebdd'	System	04 Sep 2020 04:57:13
User entered 'Yes (Y)'	System	04 Sep 2020 04:57:13

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:27:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-04T00:57:02', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'b66334ef-7235-4c90-b482-21ef7651ebdd'	System	04 Sep 2020 04:57:13
User entered '98.8'	System	04 Sep 2020 04:57:13

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-04T00:57:08', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'b66334ef-7235-4c90-b482-21ef7651ebdd'	System	04 Sep 2020 04:57:13
User entered 'No (N)'	System	04 Sep 2020 04:57:13

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:27:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-04T00:57:09', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'b66334ef-7235-4c90-b482-21ef7651ebdd'	System	04 Sep 2020 04:57:13
User entered '04 Sep 2020 00:57'	System	04 Sep 2020 04:57:13

US3742148

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:27:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 21:27:18



**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	28 Aug 2020 21:27:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-28T17:47:35', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '126c04af-9520-42a3-8f8a-2a063d7a4e2b'	System	28 Aug 2020 21:48:03
User entered 'None (1)'	System	28 Aug 2020 21:48:03

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-28T17:47:40', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '126c04af-9520-42a3-8f8a-2a063d7a4e2b'	System	28 Aug 2020 21:48:03
User entered 'No (N)'	System	28 Aug 2020 21:48:03

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-28T17:47:43', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '126c04af-9520-42a3-8f8a-2a063d7a4e2b'	System	28 Aug 2020 21:48:03
User entered 'No (N)'	System	28 Aug 2020 21:48:03

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-28T17:47:55', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '126c04af-9520-42a3-8f8a-2a063d7a4e2b'	System	28 Aug 2020 21:48:03
User entered 'None (1)'	System	28 Aug 2020 21:48:03

**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-28T17:47:58', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '126c04af-9520-42a3-8f8a-2a063d7a4e2b'	System	28 Aug 2020 21:48:03
User entered '28 Aug 2020 17:47'	System	28 Aug 2020 21:48:03

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '28 Aug 2020 17:33'	System	28 Aug 2020 21:27:18



**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '28 Aug 2020 20:03'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	28 Aug 2020 21:27:18
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-28T22:21:30', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '2491e054-53ee-4fb2-83c4-6696b8de367d'	System	29 Aug 2020 02:21:41
User entered 'Does not interfere with activity (2)'	System	29 Aug 2020 02:21:41

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-28T22:21:09', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '2491e054-53ee-4fb2-83c4-6696b8de367d'	System	29 Aug 2020 02:21:41
User entered 'No (N)'	System	29 Aug 2020 02:21:41

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-28T22:21:18', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '2491e054-53ee-4fb2-83c4-6696b8de367d'	System	29 Aug 2020 02:21:41
User entered 'No (N)'	System	29 Aug 2020 02:21:41

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-28T22:21:24', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '2491e054-53ee-4fb2-83c4-6696b8de367d'	System	29 Aug 2020 02:21:41
User entered 'None (1)'	System	29 Aug 2020 02:21:41

**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-28T22:21:35', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '2491e054-53ee-4fb2-83c4-6696b8de367d' User entered '28 Aug 2020 22:21'	System	29 Aug 2020 02:21:41
	System	29 Aug 2020 02:21:41

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '28 Aug 2020 20:58'	System	28 Aug 2020 21:27:18



**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	28 Aug 2020 21:27:18
User entered 'Day 2'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-29T21:42:30', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'f17905af-9dff-4d95-8684-cf85177fe9b0'	System	30 Aug 2020 01:43:42
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	30 Aug 2020 01:43:42

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-29T21:42:44', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'f17905af-9dff-4d95-8684-cf85177fe9b0'	System	30 Aug 2020 01:43:42
User entered 'No (N)'	System	30 Aug 2020 01:43:42

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-29T21:42:58', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'f17905af-9dff-4d95-8684-cf85177fe9b0'	System	30 Aug 2020 01:43:42
User entered 'No (N)'	System	30 Aug 2020 01:43:42

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-29T21:43:37', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'f17905af-9dff-4d95-8684-cf85177fe9b0'	System	30 Aug 2020 01:43:42
User entered 'None (1)'	System	30 Aug 2020 01:43:42

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:27:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-29T21:43:40', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'f17905af-9dff-4d95-8684-cf85177fe9b0'	System	30 Aug 2020 01:43:42
User entered '29 Aug 2020 21:43'	System	30 Aug 2020 01:43:42

**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 21:27:18



**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	28 Aug 2020 21:27:18
User entered 'Day 3'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-31T08:41:40', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '871fad00-8c2a-4b35-bbfc-b478c755fb9e'	System	31 Aug 2020 12:42:10
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	31 Aug 2020 12:42:10

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:27:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-31T08:41:46', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '871fad00-8c2a-4b35-bbfc-b478c755fb9e'	System	31 Aug 2020 12:42:10
User entered 'No (N)'	System	31 Aug 2020 12:42:10

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-31T08:41:51', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '871fad00-8c2a-4b35-bbfc-b478c755fb9e'	System	31 Aug 2020 12:42:10
User entered 'No (N)'	System	31 Aug 2020 12:42:10

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-31T08:42:03', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '871fad00-8c2a-4b35-bbfc-b478c755fb9e'	System	31 Aug 2020 12:42:10
User entered 'None (1)'	System	31 Aug 2020 12:42:10

**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-31T08:42:06', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '871fad00-8c2a-4b35-bbfc-b478c755fb9e'	System	31 Aug 2020 12:42:10
User entered '31 Aug 2020 08:42'	System	31 Aug 2020 12:42:10

**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 21:27:18



**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	28 Aug 2020 21:27:18
User entered 'Day 4'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-01T00:17:42', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '59835f5c-98fc-4e73-9611-7080dbf40694'	System	01 Sep 2020 04:18:03
User entered 'Does not interfere with activity (2)'	System	01 Sep 2020 04:18:03

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:27:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-01T00:17:46', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '59835f5c-98fc-4e73-9611-7080dbf40694'	System	01 Sep 2020 04:18:03
User entered 'No (N)'	System	01 Sep 2020 04:18:03

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-01T00:17:49', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '59835f5c-98fc-4e73-9611-7080dbf40694'	System	01 Sep 2020 04:18:03
User entered 'No (N)'	System	01 Sep 2020 04:18:03

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-01T00:17:56', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '59835f5c-98fc-4e73-9611-7080dbf40694'	System	01 Sep 2020 04:18:03
User entered 'None (1)'	System	01 Sep 2020 04:18:03

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:27:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-01T00:17:59', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '59835f5c-98fc-4e73-9611-7080dbf40694'	System	01 Sep 2020 04:18:03
User entered '01 Sep 2020 00:17'	System	01 Sep 2020 04:18:03

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:27:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 21:27:18



**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	28 Aug 2020 21:27:18
User entered 'Day 5'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-02T09:50:34', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'fb7bb99b-e338-4539-91f0-a60f72c7f88a'	System	02 Sep 2020 13:50:47
User entered 'None (1)'	System	02 Sep 2020 13:50:47

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-02T09:50:37', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'fb7bb99b-e338-4539-91f0-a60f72c7f88a'	System	02 Sep 2020 13:50:47
User entered 'No (N)'	System	02 Sep 2020 13:50:47

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-02T09:50:39', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'fb7bb99b-e338-4539-91f0-a60f72c7f88a'	System	02 Sep 2020 13:50:47
User entered 'No (N)'	System	02 Sep 2020 13:50:47

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-02T09:50:41', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'fb7bb99b-e338-4539-91f0-a60f72c7f88a'	System	02 Sep 2020 13:50:47
User entered 'None (1)'	System	02 Sep 2020 13:50:47

**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-02T09:50:43', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'fb7bb99b-e338-4539-91f0-a60f72c7f88a'	System	02 Sep 2020 13:50:47
User entered '02 Sep 2020 09:50'	System	02 Sep 2020 13:50:47

**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 21:27:18



**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	28 Aug 2020 21:27:18
User entered 'Day 6'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-03T01:08:03', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'ecc667c6-7379-4346-93f7-d552fe374959'	System	03 Sep 2020 05:08:18
User entered 'None (1)'	System	03 Sep 2020 05:08:18

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:27:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-03T01:08:06', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'ecc667c6-7379-4346-93f7-d552fe374959'	System	03 Sep 2020 05:08:18
User entered 'No (N)'	System	03 Sep 2020 05:08:18

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-03T01:08:08', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'ecc667c6-7379-4346-93f7-d552fe374959'	System	03 Sep 2020 05:08:18
User entered 'No (N)'	System	03 Sep 2020 05:08:18

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-03T01:08:10', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'ecc667c6-7379-4346-93f7-d552fe374959'	System	03 Sep 2020 05:08:18
User entered 'None (1)'	System	03 Sep 2020 05:08:18

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:27:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-03T01:08:13', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'ecc667c6-7379-4346-93f7-d552fe374959'	System	03 Sep 2020 05:08:18
User entered '03 Sep 2020 01:08'	System	03 Sep 2020 05:08:18

**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 21:27:18



**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	28 Aug 2020 21:27:18
User entered 'Day 7'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-04T00:56:21', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5b72e735-a8bb-4490-8dcf-92ab391d812e'	System	04 Sep 2020 04:56:36
User entered 'None (1)'	System	04 Sep 2020 04:56:36

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:27:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-04T00:56:23', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5b72e735-a8bb-4490-8dcf-92ab391d812e'	System	04 Sep 2020 04:56:36
User entered 'No (N)'	System	04 Sep 2020 04:56:36

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-04T00:56:25', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5b72e735-a8bb-4490-8dcf-92ab391d812e'	System	04 Sep 2020 04:56:36
User entered 'No (N)'	System	04 Sep 2020 04:56:36

US3742148

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-04T00:56:27', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5b72e735-a8bb-4490-8dcf-92ab391d812e'	System	04 Sep 2020 04:56:36
User entered 'None (1)'	System	04 Sep 2020 04:56:36

**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-04T00:56:29', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5b72e735-a8bb-4490-8dcf-92ab391d812e'	System	04 Sep 2020 04:56:36
User entered '04 Sep 2020 00:56'	System	04 Sep 2020 04:56:36

**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 21:27:18



**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 21:27:18

**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	28 Aug 2020 21:27:18
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-28T17:48:06', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'baf3a3d8-c3d4-4685-8336-4f4616e344d3'	System	28 Aug 2020 21:48:24
User entered 'None (0)'	System	28 Aug 2020 21:48:24

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-28T17:48:07', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'baf3a3d8-c3d4-4685-8336-4f4616e344d3'	System	28 Aug 2020 21:48:24
User entered 'None (0)'	System	28 Aug 2020 21:48:24

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-28T17:48:10', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'baf3a3d8-c3d4-4685-8336-4f4616e344d3'	System	28 Aug 2020 21:48:24
User entered 'None (0)'	System	28 Aug 2020 21:48:24

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-28T17:48:11', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'baf3a3d8-c3d4-4685-8336-4f4616e344d3'	System	28 Aug 2020 21:48:24
User entered 'None (0)'	System	28 Aug 2020 21:48:24

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-28T17:48:13', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'baf3a3d8-c3d4-4685-8336-4f4616e344d3'	System	28 Aug 2020 21:48:24
User entered 'None (0)'	System	28 Aug 2020 21:48:24

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-28T17:48:15', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'baf3a3d8-c3d4-4685-8336-4f4616e344d3'	System	28 Aug 2020 21:48:24
User entered 'None (0)'	System	28 Aug 2020 21:48:24



US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-28T17:48:20', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'baf3a3d8-c3d4-4685-8336-4f4616e344d3'	System	28 Aug 2020 21:48:24
User entered 'No (N)'	System	28 Aug 2020 21:48:24

**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-28T17:48:22', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'baf3a3d8-c3d4-4685-8336-4f4616e344d3'	System	28 Aug 2020 21:48:24
User entered '28 Aug 2020 17:48'	System	28 Aug 2020 21:48:24

**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '28 Aug 2020 17:33'	System	28 Aug 2020 21:27:18

**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '28 Aug 2020 20:03'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	28 Aug 2020 21:27:18
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-28T22:21:43', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '6c22bb64-bca7-4c06-abe8-f28babb082fa'	System	29 Aug 2020 02:22:09
User entered 'None (0)'	System	29 Aug 2020 02:22:09

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-28T22:21:46', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '6c22bb64-bca7-4c06-abe8-f28babb082fa'	System	29 Aug 2020 02:22:09
User entered 'None (0)'	System	29 Aug 2020 02:22:09

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-28T22:21:48', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '6c22bb64-bca7-4c06-abe8-f28babb082fa'	System	29 Aug 2020 02:22:09
User entered 'None (0)'	System	29 Aug 2020 02:22:09



US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-28T22:21:50', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '6c22bb64-bca7-4c06-abe8-f28babb082fa'	System	29 Aug 2020 02:22:09
User entered 'None (0)'	System	29 Aug 2020 02:22:09

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-28T22:21:53', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '6c22bb64-bca7-4c06-abe8-f28babb082fa'	System	29 Aug 2020 02:22:09
User entered 'None (0)'	System	29 Aug 2020 02:22:09

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-28T22:21:54', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '6c22bb64-bca7-4c06-abe8-f28babb082fa'	System	29 Aug 2020 02:22:09
User entered 'None (0)'	System	29 Aug 2020 02:22:09

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-28T22:21:58', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '6c22bb64-bca7-4c06-abe8-f28babb082fa'	System	29 Aug 2020 02:22:09
User entered 'No (N)'	System	29 Aug 2020 02:22:09

**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-28T22:22:01', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '6c22bb64-bca7-4c06-abe8-f28babb082fa'	System	29 Aug 2020 02:22:09
User entered '28 Aug 2020 22:22'	System	29 Aug 2020 02:22:09

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '28 Aug 2020 20:58'	System	28 Aug 2020 21:27:18

**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	28 Aug 2020 21:27:18
User entered 'Day 2'	System	28 Aug 2020 21:27:18



US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:27:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-29T21:43:47', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5c2fd6ac-c7f9-444b-ab61-862f7a3775fc'	System	30 Aug 2020 01:44:19
User entered 'None (0)'	System	30 Aug 2020 01:44:19

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:27:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-29T21:43:53', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5c2fd6ac-c7f9-444b-ab61-862f7a3775fc'	System	30 Aug 2020 01:44:19
User entered 'None (0)'	System	30 Aug 2020 01:44:19

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:27:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-29T21:43:55', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5c2fd6ac-c7f9-444b-ab61-862f7a3775fc'	System	30 Aug 2020 01:44:19
User entered 'None (0)'	System	30 Aug 2020 01:44:19

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:27:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-29T21:44:02', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5c2fd6ac-c7f9-444b-ab61-862f7a3775fc'	System	30 Aug 2020 01:44:19
User entered 'None (0)'	System	30 Aug 2020 01:44:19

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:27:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-29T21:44:05', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5c2fd6ac-c7f9-444b-ab61-862f7a3775fc'	System	30 Aug 2020 01:44:19
User entered 'None (0)'	System	30 Aug 2020 01:44:19

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:27:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-29T21:44:07', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5c2fd6ac-c7f9-444b-ab61-862f7a3775fc'	System	30 Aug 2020 01:44:19
User entered 'None (0)'	System	30 Aug 2020 01:44:19

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-29T21:44:12', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5c2fd6ac-c7f9-444b-ab61-862f7a3775fc'	System	30 Aug 2020 01:44:19
User entered 'No (N)'	System	30 Aug 2020 01:44:19

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:27:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-29T21:44:15', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5c2fd6ac-c7f9-444b-ab61-862f7a3775fc'	System	30 Aug 2020 01:44:19
User entered '29 Aug 2020 21:44'	System	30 Aug 2020 01:44:19



US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:27:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 21:27:18

**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	28 Aug 2020 21:27:18
User entered 'Day 3'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:27:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-31T08:41:04', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5f8ff1df-e910-455f-b615-af94b26deff6'	System	31 Aug 2020 12:41:37
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	31 Aug 2020 12:41:37

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:27:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-31T08:41:10', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5f8ff1df-e910-455f-b615-af94b26deff6'	System	31 Aug 2020 12:41:37
User entered 'Some interference with activity (2)'	System	31 Aug 2020 12:41:37

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:27:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-31T08:41:16', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5f8ff1df-e910-455f-b615-af94b26deff6'	System	31 Aug 2020 12:41:37
User entered 'No interference with activity (1)'	System	31 Aug 2020 12:41:37

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:27:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-31T08:41:20', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5f8ff1df-e910-455f-b615-af94b26deff6'	System	31 Aug 2020 12:41:37
User entered 'None (0)'	System	31 Aug 2020 12:41:37

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:27:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-31T08:41:22', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5f8ff1df-e910-455f-b615-af94b26deff6'	System	31 Aug 2020 12:41:37
User entered 'None (0)'	System	31 Aug 2020 12:41:37



US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:27:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-31T08:41:24', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5f8ff1df-e910-455f-b615-af94b26deff6'	System	31 Aug 2020 12:41:37
User entered 'None (0)'	System	31 Aug 2020 12:41:37

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-31T08:41:28', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5f8ff1df-e910-455f-b615-af94b26deff6'	System	31 Aug 2020 12:41:37
User entered 'No (N)'	System	31 Aug 2020 12:41:37

**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-08-31T08:41:31', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5f8ff1df-e910-455f-b615-af94b26deff6'	System	31 Aug 2020 12:41:37
User entered '31 Aug 2020 08:41'	System	31 Aug 2020 12:41:37

**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 21:27:18

**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	28 Aug 2020 21:27:18
User entered 'Day 4'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:27:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-01T00:17:13', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '09fc2cc3-ffdb-427e-a0ac-154eacbd4339'	System	01 Sep 2020 04:17:34
User entered 'None (0)'	System	01 Sep 2020 04:17:34

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:27:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-01T00:17:15', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '09fc2cc3-ffdb-427e-a0ac-154eacbd4339'	System	01 Sep 2020 04:17:34
User entered 'None (0)'	System	01 Sep 2020 04:17:34



US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:27:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-01T00:17:18', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '09fc2cc3-ffdb-427e-a0ac-154eacbd4339'	System	01 Sep 2020 04:17:34
User entered 'None (0)'	System	01 Sep 2020 04:17:34

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:27:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-01T00:17:21', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '09fc2cc3-ffdb-427e-a0ac-154eacbd4339'	System	01 Sep 2020 04:17:34
User entered 'None (0)'	System	01 Sep 2020 04:17:34

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:27:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-01T00:17:23', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '09fc2cc3-ffdb-427e-a0ac-154eacbd4339'	System	01 Sep 2020 04:17:34
User entered 'None (0)'	System	01 Sep 2020 04:17:34

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:27:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-01T00:17:25', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '09fc2cc3-ffdb-427e-a0ac-154eacbd4339'	System	01 Sep 2020 04:17:34
User entered 'None (0)'	System	01 Sep 2020 04:17:34

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-01T00:17:28', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '09fc2cc3-ffdb-427e-a0ac-154eacbd4339'	System	01 Sep 2020 04:17:34
User entered 'No (N)'	System	01 Sep 2020 04:17:34

**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-01T00:17:31', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '09fc2cc3-ffdb-427e-a0ac-154eacbd4339'	System	01 Sep 2020 04:17:34
User entered '01 Sep 2020 00:17'	System	01 Sep 2020 04:17:34

**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 21:27:18

**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 21:27:18



US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	28 Aug 2020 21:27:18
User entered 'Day 5'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:27:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-02T09:50:12', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '13880f35-f020-4d36-a97d-d1c63417d1f2'	System	02 Sep 2020 13:50:33
User entered 'None (0)'	System	02 Sep 2020 13:50:33

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:27:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-02T09:50:14', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '13880f35-f020-4d36-a97d-d1c63417d1f2'	System	02 Sep 2020 13:50:33
User entered 'None (0)'	System	02 Sep 2020 13:50:33

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:27:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-02T09:50:15', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '13880f35-f020-4d36-a97d-d1c63417d1f2'	System	02 Sep 2020 13:50:33
User entered 'None (0)'	System	02 Sep 2020 13:50:33

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:27:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-02T09:50:17', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '13880f35-f020-4d36-a97d-d1c63417d1f2'	System	02 Sep 2020 13:50:33
User entered 'None (0)'	System	02 Sep 2020 13:50:33

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:27:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-02T09:50:18', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '13880f35-f020-4d36-a97d-d1c63417d1f2'	System	02 Sep 2020 13:50:33
User entered 'None (0)'	System	02 Sep 2020 13:50:33

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:27:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-02T09:50:20', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '13880f35-f020-4d36-a97d-d1c63417d1f2'	System	02 Sep 2020 13:50:33
User entered 'None (0)'	System	02 Sep 2020 13:50:33

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-02T09:50:22', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '13880f35-f020-4d36-a97d-d1c63417d1f2'	System	02 Sep 2020 13:50:33
User entered 'No (N)'	System	02 Sep 2020 13:50:33



US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:27:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-02T09:50:27', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '13880f35-f020-4d36-a97d-d1c63417d1f2'	System	02 Sep 2020 13:50:33
User entered '02 Sep 2020 09:50'	System	02 Sep 2020 13:50:33

**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:27:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	28 Aug 2020 21:27:18
User entered 'Day 6'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:27:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-03T01:08:17', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '0181fceb-1710-432a-acf9-32293369de1d' User entered 'None (0)'	System	03 Sep 2020 05:08:37
	System	03 Sep 2020 05:08:37

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:27:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-03T01:08:18', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '0181fceb-1710-432a-acf9-32293369de1d' User entered 'None (0)'	System	03 Sep 2020 05:08:37
	System	03 Sep 2020 05:08:37

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:27:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-03T01:08:20', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '0181fceb-1710-432a-acf9-32293369de1d' User entered 'None (0)'	System	03 Sep 2020 05:08:37
	System	03 Sep 2020 05:08:37

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:27:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-03T01:08:22', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '0181fceb-1710-432a-acf9-32293369de1d' User entered 'None (0)'	System	03 Sep 2020 05:08:37
	System	03 Sep 2020 05:08:37



US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:27:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-03T01:08:24', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '0181fceb-1710-432a-acf9-32293369de1d' User entered 'None (0)'	System	03 Sep 2020 05:08:37
	System	03 Sep 2020 05:08:37

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:27:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-03T01:08:25', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '0181fceb-1710-432a-acf9-32293369de1d' User entered 'None (0)'	System	03 Sep 2020 05:08:37
	System	03 Sep 2020 05:08:37

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-03T01:08:28', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '0181fceb-1710-432a-acf9-32293369de1d' User entered 'No (N)'	System	03 Sep 2020 05:08:37
	System	03 Sep 2020 05:08:37

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:27:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-03T01:08:32', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '0181fceb-1710-432a-acf9-32293369de1d' User entered '03 Sep 2020 01:08'	System	03 Sep 2020 05:08:37
	System	03 Sep 2020 05:08:37

**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 21:27:18

**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	28 Aug 2020 21:27:18
User entered 'Day 7'	System	28 Aug 2020 21:27:18

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:27:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-04T00:56:03', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '0e1f91f8-96ce-41b8-8a52-17a692ef3c33'	System	04 Sep 2020 04:56:21
User entered 'None (0)'	System	04 Sep 2020 04:56:21



US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:27:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-04T00:56:05', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '0e1f91f8-96ce-41b8-8a52-17a692ef3c33'	System	04 Sep 2020 04:56:21
User entered 'None (0)'	System	04 Sep 2020 04:56:21

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:27:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-04T00:56:07', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '0e1f91f8-96ce-41b8-8a52-17a692ef3c33'	System	04 Sep 2020 04:56:21
User entered 'None (0)'	System	04 Sep 2020 04:56:21

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:27:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-04T00:56:09', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '0e1f91f8-96ce-41b8-8a52-17a692ef3c33'	System	04 Sep 2020 04:56:21
User entered 'None (0)'	System	04 Sep 2020 04:56:21

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:27:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-04T00:56:11', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '0e1f91f8-96ce-41b8-8a52-17a692ef3c33'	System	04 Sep 2020 04:56:21
User entered 'None (0)'	System	04 Sep 2020 04:56:21

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:27:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-04T00:56:13', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '0e1f91f8-96ce-41b8-8a52-17a692ef3c33'	System	04 Sep 2020 04:56:21
User entered 'None (0)'	System	04 Sep 2020 04:56:21

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-04T00:56:15', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '0e1f91f8-96ce-41b8-8a52-17a692ef3c33'	System	04 Sep 2020 04:56:21
User entered 'No (N)'	System	04 Sep 2020 04:56:21

US3742148

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:27:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-04T00:56:17', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '0e1f91f8-96ce-41b8-8a52-17a692ef3c33'	System	04 Sep 2020 04:56:21
User entered '04 Sep 2020 00:56'	System	04 Sep 2020 04:56:21

**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 21:27:18



**US3742148**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 21:27:18

**US3742148**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:27:01**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered 'Yes (Y)'	Faith Pa'ahana-Brown (b) (4)	04 Sep 2020 20:35:21

US3742148

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered '4 Sep 2020'	Faith Pa'ahana-Brown (b) (4)	04 Sep 2020 20:35:21

**US3742148**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:27:01**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered 'Contact Made (CONTACT MADE)'	Faith Pa'ahana-Brown (b) (4)	04 Sep 2020 20:35:21

US3742148

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:01

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered empty.	Faith Pa'ahana-Brown (b) (4)	04 Sep 2020 20:35:21

US3742148

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered 'Yes (Y)'	Faith Pa'ahana-Brown (b) (4)	04 Sep 2020 20:35:27

**US3742148**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:27:01**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:32
User entered 'I'	System	04 Sep 2020 20:35:27

**US3742148**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:27:01**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered 'Yes (Y)'	Faith Pa'ahana-Brown (b) (4)	11 Sep 2020 22:52:55



**US3742148**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered '11 Sep 2020'	Faith Pa'ahana-Brown (b) (4)	11 Sep 2020 22:52:55

US3742148

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Faith Pa'ahana-Brown (b) (4)	11 Sep 2020 22:52:55

**US3742148**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:27:01**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered empty.	Faith Pa'ahana-Brown (b) (4)	11 Sep 2020 22:52:55

US3742148

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered 'Yes (Y)'	Faith Pa'ahana-Brown (b) (4)	11 Sep 2020 22:53:01

**US3742148**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:27:01**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:32
User entered 'I'	System	11 Sep 2020 22:53:01

**US3742148**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:27:01**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered 'Yes (Y)'	Faith Pa'ahana-Brown (b) (4)	18 Sep 2020 17:46:53

**US3742148**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:27:01**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered '18 Sep 2020'	Faith Pa'ahana-Brown (b) (4)	18 Sep 2020 17:46:53

**US3742148**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:27:01**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered 'Contact Made (CONTACT MADE)'	Faith Pa'ahana-Brown (b) (4)	18 Sep 2020 17:46:53



US3742148

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:01

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered empty.	Faith Pa'ahana-Brown (b) (4)	18 Sep 2020 17:46:53

US3742148

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered 'Yes (Y)'	Faith Pa'ahana-Brown (b) (4)	18 Sep 2020 17:46:59

**US3742148**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:27:01**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:32
User entered '1'	System	18 Sep 2020 17:46:59

US3742148

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:27:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Oct 2020 17:43:17

US3742148

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '25 Sep 2020'	Hassan Haji (b) (4)	16 Oct 2020 17:43:17

US3742148

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:27:01

[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 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'Clinic (Clinic)'	Hassan Haji (b) (4)	16 Oct 2020 17:43:17

**US3742148**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:27:01**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered 'VISIT2'	System	16 Oct 2020 17:43:17

US3742148

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User accepted default value 'Pre-Dose (PREDOSE)'	Hassan Haji (b) (4) (b) (4)	16 Oct 2020 17:44:50



US3742148

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Oct 2020 17:44:50

US3742148

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '25 Sep 2020'	Hassan Haji (b) (4)	16 Oct 2020 17:44:50

US3742148

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '15:31'	Hassan Haji (b) (4)	16 Oct 2020 17:44:50

**US3742148**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered '25 Sep 2020 15:31'	System	16 Oct 2020 17:44:50

US3742148

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '098.8' F	Hassan Haji (b) (4)	16 Oct 2020 17:44:50

US3742148

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'Oral (Oral)'	Hassan Haji (b) (4)	16 Oct 2020 17:44:50

US3742148

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered empty.	Hassan Haji (b) (4)	16 Oct 2020 17:44:50

US3742148

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '092'	Hassan Haji (b) (4)	16 Oct 2020 17:44:50



US3742148

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered 'bpm'	System	16 Oct 2020 17:44:50

US3742148

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '16'	Hassan Haji (b) (4)	16 Oct 2020 17:44:50

US3742148

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered 'breaths/min'	System	16 Oct 2020 17:44:50

US3742148

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '105'	Hassan Haji (b) (4)	16 Oct 2020 17:44:50

US3742148

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered 'mmHg'	System	16 Oct 2020 17:44:50

US3742148

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '069'	Hassan Haji (b) (4)	16 Oct 2020 17:44:50

US3742148

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:27:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered 'mmHg'	System	16 Oct 2020 17:44:50

US3742148

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:01

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User accepted default value 'Post-Dose (POSTDOSE)'	Hassan Haji (b) (4) (b) (4)	16 Oct 2020 17:44:50



US3742148

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Oct 2020 17:44:50

US3742148

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '25 Sep 2020'	Hassan Haji (b) (4)	16 Oct 2020 17:44:50

US3742148

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '16:52'	Hassan Haji (b) (4)	16 Oct 2020 17:44:50

US3742148

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered '25 Sep 2020 16:52'	System	16 Oct 2020 17:44:50

US3742148

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '98.6' F	Hassan Haji (b) (4)	16 Oct 2020 17:44:50

US3742148

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'Oral (Oral)'	Hassan Haji (b) (4)	16 Oct 2020 17:44:50

US3742148

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered empty.	(b) (4) Hassan Haji (b) (4) (b) (4)	16 Oct 2020 17:44:50

US3742148

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '080'	Hassan Haji (b) (4)	16 Oct 2020 17:44:50



US3742148

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:01

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered 'bpm'	System	16 Oct 2020 17:44:50

US3742148

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '16'	Hassan Haji (b) (4)	16 Oct 2020 17:44:50

US3742148

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered 'breaths/min'	System	16 Oct 2020 17:44:50

US3742148

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '106'	Hassan Haji (b) (4)	16 Oct 2020 17:44:50

US3742148

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered 'mmHg'	System	16 Oct 2020 17:44:50

US3742148

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '070'	Hassan Haji (b) (4)	16 Oct 2020 17:44:50

US3742148

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:27:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered 'mmHg'	System	16 Oct 2020 17:44:50

US3742148

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:27:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Oct 2020 17:45:51



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Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:27:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '25 Sep 2020'	Hassan Haji (b) (4)	16 Oct 2020 17:45:51

US3742148

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:27:01

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Oct 2020 17:46:11

US3742148

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:27:01

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '25 Sep 2020'	(b) (4) Hassan Haji (b) (4) (b) (4)	16 Oct 2020 17:46:11

US3742148

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:27:01

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'Urine (URINE)'	Hassan Haji (b) (4)	16 Oct 2020 17:46:11

US3742148

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:27:01

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'Negative (NEGATIVE)'	Hassan Haji (b) (4)	16 Oct 2020 17:46:11

US3742148

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 09:27:01

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'No (N)'	Hassan Haji (b) (4)	16 Oct 2020 17:46:11

**US3742148**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:27:01**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered empty.	Hassan Haji (b) (4)	16 Oct 2020 17:46:11

**US3742148**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:27:01**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered empty.	Hassan Haji (b) (4)	16 Oct 2020 17:46:11



**US3742148**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered empty.	System	16 Oct 2020 17:46:11

US3742148

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:27:01

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 20:25:25

US3742148

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:27:01

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 20:25:25

US3742148

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:27:01

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 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Sep 2020 20:25:25

US3742148

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:27:01

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered 'MRNA-1273 OR PLACEBO'	System	25 Sep 2020 20:25:25

US3742148

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:27:01

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '25 Sep 2020'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 20:25:25

US3742148

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:27:01

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '16:22' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	25 Sep 2020 20:25:53
User entered '16:52'	(b) (4), (b) (6)	25 Sep 2020 20:25:25

**US3742148**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:27:01**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered '25 Sep 2020 16:22'	System	25 Sep 2020 20:25:53
User entered '25 Sep 2020 16:52'	System	25 Sep 2020 20:25:25



US3742148

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:27:01

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 20:25:25

US3742148

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:27:01

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered 'ONCE'	System	25 Sep 2020 20:25:25

US3742148

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:27:01

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered 'INTRAMUSCULAR'	System	25 Sep 2020 20:25:25

US3742148

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:27:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Oct 2020 17:46:55

US3742148

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:27:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '25 Sep 2020'	Hassan Haji (b) (4)	16 Oct 2020 17:46:55

US3742148

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:27:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '15:50'	Hassan Haji (b) (4)	16 Oct 2020 17:46:55

**US3742148**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered '25 Sep 2020 15:50'	System	16 Oct 2020 17:46:55

US3742148

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:27:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '25 Sep 2020'	Hassan Haji (b) (4)	16 Oct 2020 17:47:12



**US3742148**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:27:01**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Hassan Haji (b) (4) (b) (4)	16 Oct 2020 17:47:12

US3742148

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:27:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Oct 2020 17:47:12

**US3742148**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:27:01**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '15:49'	Hassan Haji (b) (4)	16 Oct 2020 17:47:12

**US3742148**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered '25 Sep 2020 15:49'	System	16 Oct 2020 17:47:12

**US3742148**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:27:01**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Hassan Haji (b) (4) (b) (4)	16 Oct 2020 17:47:12

US3742148

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:27:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'No (N)'	Hassan Haji (b) (4)	16 Oct 2020 17:47:12

US3742148

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:27:01

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered empty.	Hassan Haji (b) (4)	16 Oct 2020 17:47:12

**US3742148**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered empty.	System	16 Oct 2020 17:47:12



US3742148

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Oct 2020 17:47:19

**US3742148**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:27:01**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered '1'	System	16 Oct 2020 17:47:19

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	25 Sep 2020 20:25:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-25T16:58:50', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'dfe890c0-5258-49ff-aed7-87519599f762'	System	25 Sep 2020 20:59:03
User entered 'Yes (Y)'	System	25 Sep 2020 20:59:03

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-25T16:58:54', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'dfe890c0-5258-49ff-aed7-87519599f762'	System	25 Sep 2020 20:59:03
User entered '98.6'	System	25 Sep 2020 20:59:03

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-25T16:58:57', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'dfe890c0-5258-49ff-aed7-87519599f762'	System	25 Sep 2020 20:59:03
User entered 'No (N)'	System	25 Sep 2020 20:59:03

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-25T16:58:59', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'dfe890c0-5258-49ff-aed7-87519599f762'	System	25 Sep 2020 20:59:03
User entered '25 Sep 2020 16:58'	System	25 Sep 2020 20:59:03

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '25 Sep 2020 16:42'	System	25 Sep 2020 20:25:53
User entered '25 Sep 2020 17:12'	System	25 Sep 2020 20:25:25



US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '25 Sep 2020 19:12'	System	25 Sep 2020 20:25:53
User entered '25 Sep 2020 19:42'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	25 Sep 2020 20:25:25
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-25T21:29:12', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5a95ecfd-0270-417d-8400-135a4cf308bf'	System	26 Sep 2020 01:32:06
User entered 'Yes (Y)'	System	26 Sep 2020 01:32:06

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-25T21:31:58', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5a95ecfd-0270-417d-8400-135a4cf308bf' User entered '99.2'	System	26 Sep 2020 01:32:06

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-25T21:32:01', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5a95ecfd-0270-417d-8400-135a4cf308bf'	System	26 Sep 2020 01:32:06
User entered 'No (N)'	System	26 Sep 2020 01:32:06

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-25T21:32:03', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5a95ecfd-0270-417d-8400-135a4cf308bf' User entered '25 Sep 2020 21:32'	System	26 Sep 2020 01:32:06
	System	26 Sep 2020 01:32:06

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '25 Sep 2020 20:07'	System	25 Sep 2020 20:25:53
User entered '25 Sep 2020 20:37'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 20:25:25



US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	25 Sep 2020 20:25:25
User entered 'Day 2'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:27:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-27T01:23:44', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'f694bb5e-bb21-4fbc-b894-be93440bf7af'	System	27 Sep 2020 05:23:56
User entered 'Yes (Y)'	System	27 Sep 2020 05:23:56

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:27:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-27T01:23:49', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'f694bb5e-bb21-4fbc-b894-be93440bf7af' User entered '98.2'	System	27 Sep 2020 05:23:56
	System	27 Sep 2020 05:23:56

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-27T01:23:51', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'f694bb5e-bb21-4fbc-b894-be93440bf7af'	System	27 Sep 2020 05:23:56
User entered 'No (N)'	System	27 Sep 2020 05:23:56

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:27:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-27T01:23:53', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'f694bb5e-bb21-4fbc-b894-be93440bf7af'	System	27 Sep 2020 05:23:56
User entered '27 Sep 2020 01:23'	System	27 Sep 2020 05:23:56

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:27:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 20:25:25

**US3742148**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	25 Sep 2020 20:25:25
User entered 'Day 3'	System	25 Sep 2020 20:25:25



US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:27:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-28T11:06:22', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '593cdf34-80a0-4f03-bad4-45b768d04a49'	System	28 Sep 2020 15:06:45
User entered 'Yes (Y)'	System	28 Sep 2020 15:06:45

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:27:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-28T11:06:28', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '593cdf34-80a0-4f03-bad4-45b768d04a49' User entered '98.1'	System	28 Sep 2020 15:06:45
	System	28 Sep 2020 15:06:45

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-28T11:06:32', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '593cdf34-80a0-4f03-bad4-45b768d04a49'	System	28 Sep 2020 15:06:45
User entered 'No (N)'	System	28 Sep 2020 15:06:45

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:27:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-28T11:06:42', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '593cdf34-80a0-4f03-bad4-45b768d04a49'	System	28 Sep 2020 15:06:45
User entered '28 Sep 2020 11:06'	System	28 Sep 2020 15:06:45

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:27:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:27:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	25 Sep 2020 20:25:25
User entered 'Day 4'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:27:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-29T00:17:40', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '32af3d51-4f4e-4044-ba2e-903aec4c5509'	System	29 Sep 2020 04:21:20
User entered 'Yes (Y)'	System	29 Sep 2020 04:21:20



US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:27:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-29T00:21:11', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '32af3d51-4f4e-4044-ba2e-903aec4c5509'	System	29 Sep 2020 04:21:20
User entered '99.0'	System	29 Sep 2020 04:21:20

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-29T00:21:13', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '32af3d51-4f4e-4044-ba2e-903aec4c5509'	System	29 Sep 2020 04:21:20
User entered 'No (N)'	System	29 Sep 2020 04:21:20

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:27:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-29T00:21:15', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '32af3d51-4f4e-4044-ba2e-903aec4c5509'	System	29 Sep 2020 04:21:20
User entered '29 Sep 2020 00:21'	System	29 Sep 2020 04:21:20

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:27:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:27:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	25 Sep 2020 20:25:25
User entered 'Day 5'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:27:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-29T22:34:21', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '803dc0b7-55e0-4bc4-92b0-4438ac14c2e6'	System	30 Sep 2020 02:37:13
User entered 'Yes (Y)'	System	30 Sep 2020 02:37:13

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:27:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-29T22:36:59', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '803dc0b7-55e0-4bc4-92b0-4438ac14c2e6' User entered '98.4'	System	30 Sep 2020 02:37:13
	System	30 Sep 2020 02:37:13



US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-29T22:37:05', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '803dc0b7-55e0-4bc4-92b0-4438ac14c2e6'	System	30 Sep 2020 02:37:13
User entered 'No (N)'	System	30 Sep 2020 02:37:13

**US3742148**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-29T22:37:08', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '803dc0b7-55e0-4bc4-92b0-4438ac14c2e6' User entered '29 Sep 2020 22:37'	System	30 Sep 2020 02:37:13
	System	30 Sep 2020 02:37:13

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:27:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:27:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	25 Sep 2020 20:25:25
User entered 'Day 6'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:27:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-30T23:11:40', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'bb7856c3-6202-4745-ac75-b47f8a1bb483'	System	01 Oct 2020 03:12:01
User entered 'Yes (Y)'	System	01 Oct 2020 03:12:01

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:27:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-30T23:11:49', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'bb7856c3-6202-4745-ac75-b47f8a1bb483'	System	01 Oct 2020 03:12:01
User entered '98.2'	System	01 Oct 2020 03:12:01

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-30T23:11:53', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'bb7856c3-6202-4745-ac75-b47f8a1bb483'	System	01 Oct 2020 03:12:01
User entered 'No (N)'	System	01 Oct 2020 03:12:01



US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:27:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-30T23:11:56', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'bb7856c3-6202-4745-ac75-b47f8a1bb483'	System	01 Oct 2020 03:12:01
User entered '30 Sep 2020 23:11'	System	01 Oct 2020 03:12:01

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:27:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:27:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	25 Sep 2020 20:25:25
User entered 'Day 7'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:27:01

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:27:01

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02



US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:27:01

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:27:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:27:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:27:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	25 Sep 2020 20:25:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-25T16:59:07', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '83922427-62c6-417f-9e00-3efcca64566f'	System	25 Sep 2020 20:59:43
User entered 'None (1)'	System	25 Sep 2020 20:59:43

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-25T16:59:25', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '83922427-62c6-417f-9e00-3efcca64566f'	System	25 Sep 2020 20:59:43
User entered 'No (N)'	System	25 Sep 2020 20:59:43

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-25T16:59:27', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '83922427-62c6-417f-9e00-3efcca64566f'	System	25 Sep 2020 20:59:43
User entered 'No (N)'	System	25 Sep 2020 20:59:43



US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-25T16:59:34', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '83922427-62c6-417f-9e00-3efcca64566f'	System	25 Sep 2020 20:59:43
User entered 'None (1)'	System	25 Sep 2020 20:59:43

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-25T16:59:38', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '83922427-62c6-417f-9e00-3efcca64566f'	System	25 Sep 2020 20:59:43
User entered '25 Sep 2020 16:59'	System	25 Sep 2020 20:59:43

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '25 Sep 2020 16:42'	System	25 Sep 2020 20:25:53
User entered '25 Sep 2020 17:12'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '25 Sep 2020 19:12'	System	25 Sep 2020 20:25:53
User entered '25 Sep 2020 19:42'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	25 Sep 2020 20:25:25
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-25T21:26:28', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'c73f233d-0fae-470b-909d-70c2fd22e71e'	System	26 Sep 2020 01:27:46
User entered 'Does not interfere with activity (2)'	System	26 Sep 2020 01:27:46

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-25T21:27:11', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'c73f233d-0fae-470b-909d-70c2fd22e71e'	System	26 Sep 2020 01:27:46
User entered 'No (N)'	System	26 Sep 2020 01:27:46

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-25T21:27:32', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'c73f233d-0fae-470b-909d-70c2fd22e71e'	System	26 Sep 2020 01:27:46
User entered 'No (N)'	System	26 Sep 2020 01:27:46



US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-25T21:27:39', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'c73f233d-0fae-470b-909d-70c2fd22e71e'	System	26 Sep 2020 01:27:46
User entered 'None (1)'	System	26 Sep 2020 01:27:46

**US3742148**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-25T21:27:42', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'c73f233d-0fae-470b-909d-70c2fd22e71e'	System	26 Sep 2020 01:27:46
User entered '25 Sep 2020 21:27'	System	26 Sep 2020 01:27:46

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '25 Sep 2020 20:07'	System	25 Sep 2020 20:25:53
User entered '25 Sep 2020 20:37'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	25 Sep 2020 20:25:25
User entered 'Day 2'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-26T22:55:10', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '06045ddd-5073-4122-8d35-a5234bed5f9c'	System	27 Sep 2020 02:57:37
User entered 'Does not interfere with activity (2)'	System	27 Sep 2020 02:57:37

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-26T22:55:17', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '06045ddd-5073-4122-8d35-a5234bed5f9c'	System	27 Sep 2020 02:57:37
User entered 'No (N)'	System	27 Sep 2020 02:57:37

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-26T22:57:15', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '06045ddd-5073-4122-8d35-a5234bed5f9c'	System	27 Sep 2020 02:57:37
User entered 'No (N)'	System	27 Sep 2020 02:57:37



US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-26T22:57:25', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '06045ddd-5073-4122-8d35-a5234bed5f9c'	System	27 Sep 2020 02:57:37
User entered 'None (1)'	System	27 Sep 2020 02:57:37

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:27:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-26T22:57:30', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '06045ddd-5073-4122-8d35-a5234bed5f9c'	System	27 Sep 2020 02:57:37
User entered '26 Sep 2020 22:57'	System	27 Sep 2020 02:57:37

**US3742148**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:27:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	25 Sep 2020 20:25:25
User entered 'Day 3'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-28T11:06:48', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5365ee6e-2605-4350-8f9f-972c0cdc7168'	System	28 Sep 2020 15:07:09
User entered 'None (1)'	System	28 Sep 2020 15:07:09

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-28T11:06:54', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5365ee6e-2605-4350-8f9f-972c0cdc7168'	System	28 Sep 2020 15:07:09
User entered 'No (N)'	System	28 Sep 2020 15:07:09

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-28T11:06:56', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5365ee6e-2605-4350-8f9f-972c0cdc7168'	System	28 Sep 2020 15:07:09
User entered 'No (N)'	System	28 Sep 2020 15:07:09



US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-28T11:07:01', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5365ee6e-2605-4350-8f9f-972c0cdc7168'	System	28 Sep 2020 15:07:09
User entered 'None (1)'	System	28 Sep 2020 15:07:09

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:27:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-28T11:07:05', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5365ee6e-2605-4350-8f9f-972c0cdc7168'	System	28 Sep 2020 15:07:09
User entered '28 Sep 2020 11:07'	System	28 Sep 2020 15:07:09

**US3742148**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:27:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	25 Sep 2020 20:25:25
User entered 'Day 4'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-29T00:17:22', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'dcd32a5e-c4a8-429d-8428-f4477b1731c1'	System	29 Sep 2020 04:17:37
User entered 'None (1)'	System	29 Sep 2020 04:17:37

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:27:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-29T00:17:25', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'dcd32a5e-c4a8-429d-8428-f4477b1731c1'	System	29 Sep 2020 04:17:37
User entered 'No (N)'	System	29 Sep 2020 04:17:37

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-29T00:17:27', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'dcd32a5e-c4a8-429d-8428-f4477b1731c1'	System	29 Sep 2020 04:17:37
User entered 'No (N)'	System	29 Sep 2020 04:17:37



US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-29T00:17:30', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'dcd32a5e-c4a8-429d-8428-f4477b1731c1'	System	29 Sep 2020 04:17:37
User entered 'None (1)'	System	29 Sep 2020 04:17:37

**US3742148**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-29T00:17:33', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'dcd32a5e-c4a8-429d-8428-f4477b1731c1' User entered '29 Sep 2020 00:17'	System	29 Sep 2020 04:17:37
	System	29 Sep 2020 04:17:37

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:27:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 20:25:25

**US3742148**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	25 Sep 2020 20:25:25
User entered 'Day 5'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-29T22:33:39', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '8775cf29-954e-4107-9c1c-a93be2ba0f70'	System	30 Sep 2020 02:33:59
User entered 'None (1)'	System	30 Sep 2020 02:33:59

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:27:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-29T22:33:43', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '8775cf29-954e-4107-9c1c-a93be2ba0f70'	System	30 Sep 2020 02:33:59
User entered 'No (N)'	System	30 Sep 2020 02:33:59

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-29T22:33:45', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '8775cf29-954e-4107-9c1c-a93be2ba0f70'	System	30 Sep 2020 02:33:59
User entered 'No (N)'	System	30 Sep 2020 02:33:59



US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-29T22:33:47', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '8775cf29-954e-4107-9c1c-a93be2ba0f70'	System	30 Sep 2020 02:33:59
User entered 'None (1)'	System	30 Sep 2020 02:33:59

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:27:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-29T22:33:54', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '8775cf29-954e-4107-9c1c-a93be2ba0f70'	System	30 Sep 2020 02:33:59
User entered '29 Sep 2020 22:33'	System	30 Sep 2020 02:33:59

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:27:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 20:25:25

**US3742148**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	25 Sep 2020 20:25:25
User entered 'Day 6'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-30T23:12:01', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'f12b98e7-6c0a-4775-81cd-90172a7be433'	System	01 Oct 2020 03:12:13
User entered 'None (1)'	System	01 Oct 2020 03:12:13

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:27:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-30T23:12:03', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'f12b98e7-6c0a-4775-81cd-90172a7be433'	System	01 Oct 2020 03:12:13
User entered 'No (N)'	System	01 Oct 2020 03:12:13

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-30T23:12:05', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'f12b98e7-6c0a-4775-81cd-90172a7be433'	System	01 Oct 2020 03:12:13
User entered 'No (N)'	System	01 Oct 2020 03:12:13



US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-30T23:12:06', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'f12b98e7-6c0a-4775-81cd-90172a7be433'	System	01 Oct 2020 03:12:13
User entered 'None (1)'	System	01 Oct 2020 03:12:13

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:27:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-30T23:12:08', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'f12b98e7-6c0a-4775-81cd-90172a7be433'	System	01 Oct 2020 03:12:13
User entered '30 Sep 2020 23:12'	System	01 Oct 2020 03:12:13

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:27:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:27:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	25 Sep 2020 20:25:25
User entered 'Day 7'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:27:01

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:27:01

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02



US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:27:01

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:27:01

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:27:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:27:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	25 Sep 2020 20:25:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-25T16:59:50', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '2f87d961-8baf-4410-93eb-4e966b94a4ce'	System	25 Sep 2020 21:00:11
User entered 'None (0)'	System	25 Sep 2020 21:00:11



US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-25T16:59:54', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '2f87d961-8baf-4410-93eb-4e966b94a4ce'	System	25 Sep 2020 21:00:11
User entered 'None (0)'	System	25 Sep 2020 21:00:11

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-25T16:59:56', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '2f87d961-8baf-4410-93eb-4e966b94a4ce'	System	25 Sep 2020 21:00:11
User entered 'None (0)'	System	25 Sep 2020 21:00:11

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-25T16:59:59', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '2f87d961-8baf-4410-93eb-4e966b94a4ce'	System	25 Sep 2020 21:00:11
User entered 'None (0)'	System	25 Sep 2020 21:00:11

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-25T17:00:00', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '2f87d961-8baf-4410-93eb-4e966b94a4ce'	System	25 Sep 2020 21:00:11
User entered 'None (0)'	System	25 Sep 2020 21:00:11

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-25T17:00:02', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '2f87d961-8baf-4410-93eb-4e966b94a4ce'	System	25 Sep 2020 21:00:11
User entered 'None (0)'	System	25 Sep 2020 21:00:11

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-25T17:00:06', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '2f87d961-8baf-4410-93eb-4e966b94a4ce'	System	25 Sep 2020 21:00:11
User entered 'No (N)'	System	25 Sep 2020 21:00:11

**US3742148**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-25T17:00:08', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '2f87d961-8baf-4410-93eb-4e966b94a4ce'	System	25 Sep 2020 21:00:11
User entered '25 Sep 2020 17:00'	System	25 Sep 2020 21:00:11

**US3742148**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '25 Sep 2020 16:42'	System	25 Sep 2020 20:25:53
User entered '25 Sep 2020 17:12'	System	25 Sep 2020 20:25:25



US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:27:01

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '25 Sep 2020 19:12'	System	25 Sep 2020 20:25:53
User entered '25 Sep 2020 19:42'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	25 Sep 2020 20:25:25
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-25T21:27:55', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '8bd09a84-2871-4afb-8388-02d6771a2a22'	System	26 Sep 2020 01:28:46
User entered 'None (0)'	System	26 Sep 2020 01:28:46

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-25T21:27:58', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '8bd09a84-2871-4afb-8388-02d6771a2a22'	System	26 Sep 2020 01:28:46
User entered 'None (0)'	System	26 Sep 2020 01:28:46

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-25T21:28:00', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '8bd09a84-2871-4afb-8388-02d6771a2a22'	System	26 Sep 2020 01:28:46
User entered 'None (0)'	System	26 Sep 2020 01:28:46

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-25T21:28:02', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '8bd09a84-2871-4afb-8388-02d6771a2a22'	System	26 Sep 2020 01:28:46
User entered 'None (0)'	System	26 Sep 2020 01:28:46

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-25T21:28:05', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '8bd09a84-2871-4afb-8388-02d6771a2a22'	System	26 Sep 2020 01:28:46
User entered 'None (0)'	System	26 Sep 2020 01:28:46

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-25T21:28:06', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '8bd09a84-2871-4afb-8388-02d6771a2a22'	System	26 Sep 2020 01:28:46
User entered 'None (0)'	System	26 Sep 2020 01:28:46



US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-25T21:28:09', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '8bd09a84-2871-4afb-8388-02d6771a2a22'	System	26 Sep 2020 01:28:46
User entered 'No (N)'	System	26 Sep 2020 01:28:46

**US3742148**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-25T21:28:40', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '8bd09a84-2871-4afb-8388-02d6771a2a22'	System	26 Sep 2020 01:28:46
User entered '25 Sep 2020 21:28'	System	26 Sep 2020 01:28:46

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:27:01

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '25 Sep 2020 20:07'	System	25 Sep 2020 20:25:53
User entered '25 Sep 2020 20:37'	System	25 Sep 2020 20:25:25

**US3742148**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	25 Sep 2020 20:25:25
User entered 'Day 2'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:27:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-26T22:54:07', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5fd2a78a-5b70-4ac7-9722-5a1ffb8a92cd' User entered 'None (0)'	System	27 Sep 2020 02:54:40
	System	27 Sep 2020 02:54:40

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:27:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-26T22:54:09', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5fd2a78a-5b70-4ac7-9722-5a1ffb8a92cd'	System	27 Sep 2020 02:54:40
User entered 'None (0)'	System	27 Sep 2020 02:54:40

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:27:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-26T22:54:12', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5fd2a78a-5b70-4ac7-9722-5a1ffb8a92cd'	System	27 Sep 2020 02:54:40
User entered 'None (0)'	System	27 Sep 2020 02:54:40



US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:27:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-26T22:54:14', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5fd2a78a-5b70-4ac7-9722-5a1ffb8a92cd'	System	27 Sep 2020 02:54:40
User entered 'None (0)'	System	27 Sep 2020 02:54:40

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:27:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-26T22:54:24', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5fd2a78a-5b70-4ac7-9722-5a1ffb8a92cd' User entered 'None (0)'	System	27 Sep 2020 02:54:40
	System	27 Sep 2020 02:54:40

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:27:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-26T22:54:27', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5fd2a78a-5b70-4ac7-9722-5a1ffb8a92cd'	System	27 Sep 2020 02:54:40
User entered 'None (0)'	System	27 Sep 2020 02:54:40

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-26T22:54:29', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5fd2a78a-5b70-4ac7-9722-5a1ffb8a92cd'	System	27 Sep 2020 02:54:40
User entered 'No (N)'	System	27 Sep 2020 02:54:40

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:27:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-26T22:54:37', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5fd2a78a-5b70-4ac7-9722-5a1ffb8a92cd' User entered '26 Sep 2020 22:54'	System	27 Sep 2020 02:54:40
	System	27 Sep 2020 02:54:40

**US3742148**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 20:25:25

**US3742148**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	25 Sep 2020 20:25:25
User entered 'Day 3'	System	25 Sep 2020 20:25:25



US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:27:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-28T11:07:09', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'b540b773-565b-4edc-90a2-43d1e3725fd9'	System	28 Sep 2020 15:07:30
User entered 'None (0)'	System	28 Sep 2020 15:07:30

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:27:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-28T11:07:11', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'b540b773-565b-4edc-90a2-43d1e3725fd9'	System	28 Sep 2020 15:07:30
User entered 'None (0)'	System	28 Sep 2020 15:07:30

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:27:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-28T11:07:13', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'b540b773-565b-4edc-90a2-43d1e3725fd9' User entered 'None (0)'	System	28 Sep 2020 15:07:30
	System	28 Sep 2020 15:07:30

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:27:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-28T11:07:15', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'b540b773-565b-4edc-90a2-43d1e3725fd9'	System	28 Sep 2020 15:07:30
User entered 'None (0)'	System	28 Sep 2020 15:07:30

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:27:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-28T11:07:17', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'b540b773-565b-4edc-90a2-43d1e3725fd9'	System	28 Sep 2020 15:07:30
User entered 'None (0)'	System	28 Sep 2020 15:07:30

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:27:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-28T11:07:19', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'b540b773-565b-4edc-90a2-43d1e3725fd9' User entered 'None (0)'	System	28 Sep 2020 15:07:30
	System	28 Sep 2020 15:07:30

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-28T11:07:21', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'b540b773-565b-4edc-90a2-43d1e3725fd9'	System	28 Sep 2020 15:07:30
User entered 'No (N)'	System	28 Sep 2020 15:07:30

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:27:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-28T11:07:24', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'b540b773-565b-4edc-90a2-43d1e3725fd9'	System	28 Sep 2020 15:07:30
User entered '28 Sep 2020 11:07'	System	28 Sep 2020 15:07:30



**US3742148**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 20:25:25

**US3742148**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	25 Sep 2020 20:25:25
User entered 'Day 4'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:27:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-29T00:17:01', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'fb54ea78-1d39-46be-9315-9eebe1dca0eb'	System	29 Sep 2020 04:17:20
User entered 'None (0)'	System	29 Sep 2020 04:17:20

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:27:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-29T00:17:03', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'fb54ea78-1d39-46be-9315-9eebe1dca0eb'	System	29 Sep 2020 04:17:20
User entered 'None (0)'	System	29 Sep 2020 04:17:20

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:27:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-29T00:17:04', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'fb54ea78-1d39-46be-9315-9eebe1dca0eb'	System	29 Sep 2020 04:17:20
User entered 'None (0)'	System	29 Sep 2020 04:17:20

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:27:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-29T00:17:06', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'fb54ea78-1d39-46be-9315-9eebe1dca0eb'	System	29 Sep 2020 04:17:20
User entered 'None (0)'	System	29 Sep 2020 04:17:20

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:27:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-29T00:17:08', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'fb54ea78-1d39-46be-9315-9eebe1dca0eb'	System	29 Sep 2020 04:17:20
User entered 'None (0)'	System	29 Sep 2020 04:17:20



US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:27:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-29T00:17:10', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'fb54ea78-1d39-46be-9315-9eebe1dca0eb'	System	29 Sep 2020 04:17:20
User entered 'None (0)'	System	29 Sep 2020 04:17:20

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-29T00:17:12', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'fb54ea78-1d39-46be-9315-9eebe1dca0eb'	System	29 Sep 2020 04:17:20
User entered 'No (N)'	System	29 Sep 2020 04:17:20

**US3742148**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-29T00:17:14', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'fb54ea78-1d39-46be-9315-9eebe1dca0eb'	System	29 Sep 2020 04:17:20
User entered '29 Sep 2020 00:17'	System	29 Sep 2020 04:17:20

**US3742148**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 20:25:25

**US3742148**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	25 Sep 2020 20:25:25
User entered 'Day 5'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:27:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-29T22:34:00', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '0515fc95-ca01-426d-809f-309c8127163f' User entered 'None (0)'	System	30 Sep 2020 02:34:20
	System	30 Sep 2020 02:34:20

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:27:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-29T22:34:02', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '0515fc95-ca01-426d-809f-309c8127163f' User entered 'None (0)'	System	30 Sep 2020 02:34:20
	System	30 Sep 2020 02:34:20



US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:27:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-29T22:34:04', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '0515fc95-ca01-426d-809f-309c8127163f' User entered 'None (0)'	System	30 Sep 2020 02:34:20
	System	30 Sep 2020 02:34:20

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:27:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-29T22:34:05', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '0515fc95-ca01-426d-809f-309c8127163f' User entered 'None (0)'	System	30 Sep 2020 02:34:20
	System	30 Sep 2020 02:34:20

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:27:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-29T22:34:07', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '0515fc95-ca01-426d-809f-309c8127163f' User entered 'None (0)'	System	30 Sep 2020 02:34:20
	System	30 Sep 2020 02:34:20

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:27:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-29T22:34:10', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '0515fc95-ca01-426d-809f-309c8127163f' User entered 'None (0)'	System	30 Sep 2020 02:34:20
	System	30 Sep 2020 02:34:20

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-29T22:34:12', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '0515fc95-ca01-426d-809f-309c8127163f' User entered 'No (N)'	System	30 Sep 2020 02:34:20
	System	30 Sep 2020 02:34:20

**US3742148**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-29T22:34:14', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '0515fc95-ca01-426d-809f-309c8127163f' User entered '29 Sep 2020 22:34'	System	30 Sep 2020 02:34:20
	System	30 Sep 2020 02:34:20

**US3742148**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 20:25:25

**US3742148**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 20:25:25



US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	25 Sep 2020 20:25:25
User entered 'Day 6'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:27:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-30T23:11:18', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'b4f2888e-2b34-4ba9-887c-12c448425992'	System	01 Oct 2020 03:11:37
User entered 'None (0)'	System	01 Oct 2020 03:11:37

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:27:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-30T23:11:20', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'b4f2888e-2b34-4ba9-887c-12c448425992'	System	01 Oct 2020 03:11:37
User entered 'None (0)'	System	01 Oct 2020 03:11:37

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:27:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-30T23:11:25', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'b4f2888e-2b34-4ba9-887c-12c448425992'	System	01 Oct 2020 03:11:37
User entered 'None (0)'	System	01 Oct 2020 03:11:37

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:27:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-30T23:11:27', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'b4f2888e-2b34-4ba9-887c-12c448425992'	System	01 Oct 2020 03:11:37
User entered 'None (0)'	System	01 Oct 2020 03:11:37

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:27:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-30T23:11:28', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'b4f2888e-2b34-4ba9-887c-12c448425992'	System	01 Oct 2020 03:11:37
User entered 'None (0)'	System	01 Oct 2020 03:11:37

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:27:01

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-30T23:11:30', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'b4f2888e-2b34-4ba9-887c-12c448425992'	System	01 Oct 2020 03:11:37
User entered 'None (0)'	System	01 Oct 2020 03:11:37

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-30T23:11:32', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'b4f2888e-2b34-4ba9-887c-12c448425992'	System	01 Oct 2020 03:11:37
User entered 'No (N)'	System	01 Oct 2020 03:11:37



US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:27:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-09-30T23:11:34', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'b4f2888e-2b34-4ba9-887c-12c448425992'	System	01 Oct 2020 03:11:37
User entered '30 Sep 2020 23:11'	System	01 Oct 2020 03:11:37

**US3742148**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 20:25:25

**US3742148**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:27:01

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	25 Sep 2020 20:25:25
User entered 'Day 7'	System	25 Sep 2020 20:25:25

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:27:01

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:27:01

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:27:01

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:27:01

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02



US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:27:01

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02

**US3742148**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:27:01**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:27:01

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 13:51:02

US3742148

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:27:01

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02

**US3742148**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 20:25:25

**US3742148**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:27:01**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 20:25:25

**US3742148**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:27:01**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Oct 2020 17:48:30

**US3742148**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered '2 Oct 2020'	Hassan Haji (b) (4)	16 Oct 2020 17:48:30



US3742148

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered 'Contact Made (CONTACT MADE)'	Hassan Haji (b) (4)	16 Oct 2020 17:48:30

US3742148

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:01

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered empty.	Hassan Haji (b) (4)	16 Oct 2020 17:48:30

US3742148

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Oct 2020 17:48:35

**US3742148**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:27:01**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:32
User entered 'I'	System	16 Oct 2020 17:48:35

**US3742148**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:27:01**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Oct 2020 17:49:52

**US3742148**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered '10 Oct 2020'	Hassan Haji (b) (4)	16 Oct 2020 17:49:52

US3742148

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered 'Contact Made (CONTACT MADE)'	Hassan Haji (b) (4)	16 Oct 2020 17:49:52

**US3742148**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:27:01**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered empty.	Hassan Haji (b) (4)	16 Oct 2020 17:49:52



US3742148

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Oct 2020 17:50:14

**US3742148**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:27:01**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:32
User entered 'I'	System	16 Oct 2020 17:50:14

US3742148

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:01

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Oct 2020 17:51:11

US3742148

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered '16 Oct 2020'	Hassan Haji (b) (4)	16 Oct 2020 17:51:11

US3742148

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:01

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered 'Contact Made (CONTACT MADE)'	Hassan Haji (b) (4)	16 Oct 2020 17:51:11

US3742148

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:01

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered empty.	Hassan Haji (b) (4)	16 Oct 2020 17:51:11

US3742148

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:32
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:16:37
User entered 'Yes (Y)'	Hassan Haji (b) (4)	16 Oct 2020 17:51:15

**US3742148**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:27:01**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:32
User entered 'I'	System	16 Oct 2020 17:51:15



US3742148

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:27:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'Yes (Y)'	Hassan Haji (b) (4)	23 Oct 2020 20:11:29

US3742148

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '23 Oct 2020'	Hassan Haji (b) (4)	23 Oct 2020 20:11:29

US3742148

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:27:01

[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 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'Clinic (Clinic)'	Hassan Haji (b) (4)	23 Oct 2020 20:11:29

**US3742148**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:27:01**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered 'VISIT3'	System	23 Oct 2020 20:11:29

US3742148

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'No (N)'	Hassan Haji (b) (4)	23 Oct 2020 20:11:34

US3742148

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 20:11:34

**US3742148**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 20:11:34

**US3742148**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered empty.	System	23 Oct 2020 20:11:34



US3742148

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 20:11:34

US3742148

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 20:11:34

**US3742148**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:27:01**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 20:11:34

**US3742148**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:27:01**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 20:11:34

**US3742148**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:27:01**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered empty.	System	23 Oct 2020 20:11:34

US3742148

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 20:11:34

US3742148

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered empty.	System	23 Oct 2020 20:11:34

US3742148

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 20:11:34



**US3742148**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:27:01**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered empty.	System	23 Oct 2020 20:11:34

US3742148

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered empty.	Hassan Haji (b) (4)	23 Oct 2020 20:11:34

US3742148

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered empty.	System	23 Oct 2020 20:11:34

US3742148

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43

US3742148

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43

US3742148

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:27:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'Yes (Y)'	Hassan Haji (b) (4)	23 Oct 2020 20:11:40

US3742148

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:27:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '23 Oct 2020'	Hassan Haji (b) (4)	23 Oct 2020 20:11:40

US3742148

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:27:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'Yes (Y)'	Hassan Haji (b) (4)	23 Oct 2020 20:11:55



US3742148

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:27:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '23 Oct 2020'	Hassan Haji (b) (4)	23 Oct 2020 20:11:55

US3742148

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:27:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered '15:21'	Hassan Haji (b) (4)	23 Oct 2020 20:11:55

**US3742148**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:27:01**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered '23 Oct 2020 15:21'	System	23 Oct 2020 20:11:55

US3742148

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	15 Feb 2021 17:21:17
User entered 'Yes (Y)'	Hassan Haji (b) (4)	23 Oct 2020 20:14:39

**US3742148**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:27:01**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered 'I'	System	23 Oct 2020 20:14:39

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	28 Aug 2020 21:27:18
User entered 'Day 64'	System	28 Aug 2020 21:27:18

US3742148

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-10-28T19:58:05', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'de6d26f5-26d1-4466-bec6-9dcaeab99e76'	System	28 Oct 2020 23:59:31
User entered 'Yes (Y)'	System	28 Oct 2020 23:59:31

US3742148

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

Have you been exposed to someone with 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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-10-28T19:58:23', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'de6d26f5-26d1-4466-bec6-9dcaeab99e76'	System	28 Oct 2020 23:59:31
User entered 'No (N)'	System	28 Oct 2020 23:59:31



US3742148

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-10-28T19:58:57', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'de6d26f5-26d1-4466-bec6-9dcaeab99e76'	System	28 Oct 2020 23:59:31
User entered 'No (N)'	System	28 Oct 2020 23:59:31

US3742148

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-10-28T19:59:23', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'de6d26f5-26d1-4466-bec6-9dcaeab99e76'	System	28 Oct 2020 23:59:31
User entered 'No (N)'	System	28 Oct 2020 23:59:31

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-10-28T19:59:27', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'de6d26f5-26d1-4466-bec6-9dcaeab99e76'	System	28 Oct 2020 23:59:31
User entered '28 Oct 2020 19:59:27'	System	28 Oct 2020 23:59:31

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	28 Aug 2020 21:27:18
User entered '28 Oct 2020 00:01'	System	28 Aug 2020 21:27:18

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	28 Aug 2020 21:27:18
User entered '01 Nov 2020 23:59'	System	28 Aug 2020 21:27:18

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	28 Aug 2020 21:27:18
User entered 'Day 71'	System	28 Aug 2020 21:27:18

US3742148

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

[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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-11-06T12:43:55', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'e02943b2-2664-4d07-8863-d39b21ed80da'	System	06 Nov 2020 17:44:48
User entered 'No (N)'	System	06 Nov 2020 17:44:48

US3742148

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

Have you been exposed to someone with 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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-11-06T12:44:08', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'e02943b2-2664-4d07-8863-d39b21ed80da'	System	06 Nov 2020 17:44:48
User entered 'No (N)'	System	06 Nov 2020 17:44:48



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-11-06T12:44:12', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'e02943b2-2664-4d07-8863-d39b21ed80da'	System	06 Nov 2020 17:44:48
User entered '06 Nov 2020 12:44:12'	System	06 Nov 2020 17:44:48

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	28 Aug 2020 21:27:18
User entered '04 Nov 2020 00:01'	System	28 Aug 2020 21:27:18

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	28 Aug 2020 21:27:18
User entered '08 Nov 2020 23:59'	System	28 Aug 2020 21:27:18

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	28 Aug 2020 21:27:18
User entered 'Day 78'	System	28 Aug 2020 21:27:18

US3742148

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

[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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-11-13T07:09:30', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '4746a5a7-6163-4a5f-88d0-b3385024a712'	System	13 Nov 2020 12:09:43
User entered 'No (N)'	System	13 Nov 2020 12:09:43

US3742148

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:27:01

Have you been exposed to someone with 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 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-11-13T07:09:35', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '4746a5a7-6163-4a5f-88d0-b3385024a712'	System	13 Nov 2020 12:09:43
User entered 'No (N)'	System	13 Nov 2020 12:09:43

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-11-13T07:09:38', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '4746a5a7-6163-4a5f-88d0-b3385024a712' User entered '13 Nov 2020 07:09:38'	System	13 Nov 2020 12:09:43
	System	13 Nov 2020 12:09:43

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	28 Aug 2020 21:27:18
User entered '11 Nov 2020 00:01'	System	28 Aug 2020 21:27:18



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 13:51:02
Data entry locked.	System	28 Aug 2020 21:27:18
User entered '15 Nov 2020 23:59'	System	28 Aug 2020 21:27:18

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[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 (1b5527e7a8ccc0c1)', Time: '2020-11-24T10:28:08', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5b8f6f6c-547d-4d28-b2a9-94d0753d0956'	System	24 Nov 2020 15:28:19
User entered 'No (N)'	System	24 Nov 2020 15:28:19

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Have you been exposed to someone with 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 (1b5527e7a8ccc0c1)', Time: '2020-11-24T10:28:12', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5b8f6f6c-547d-4d28-b2a9-94d0753d0956'	System	24 Nov 2020 15:28:19
User entered 'No (N)'	System	24 Nov 2020 15:28:19

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-11-24T10:28:15', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5b8f6f6c-547d-4d28-b2a9-94d0753d0956'	System	24 Nov 2020 15:28:19
User entered '24 Nov 2020 10:28:15'	System	24 Nov 2020 15:28:19

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 20:17:55



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[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 (1b5527e7a8ccc0c1)', Time: '2020-12-02T22:20:01', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'd97d43f8-fb33-44c1-b970-1ad492db4959'	System	03 Dec 2020 03:20:12
User entered 'No (N)'	System	03 Dec 2020 03:20:12

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Have you been exposed to someone with 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 (1b5527e7a8ccc0c1)', Time: '2020-12-02T22:20:05', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'd97d43f8-fb33-44c1-b970-1ad492db4959'	System	03 Dec 2020 03:20:12
User entered 'No (N)'	System	03 Dec 2020 03:20:12

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-12-02T22:20:08', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'd97d43f8-fb33-44c1-b970-1ad492db4959'	System	03 Dec 2020 03:20:12
User entered '02 Dec 2020 22:20:08'	System	03 Dec 2020 03:20:12

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[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 (1b5527e7a8ccc0c1)', Time: '2020-12-07T15:36:45', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'cf2b2012-d2f8-46e3-8756-8ff27395e37a'	System	07 Dec 2020 20:36:55
User entered 'No (N)'	System	07 Dec 2020 20:36:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Have you been exposed to someone with 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 (1b5527e7a8ccc0c1)', Time: '2020-12-07T15:36:48', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'cf2b2012-d2f8-46e3-8756-8ff27395e37a'	System	07 Dec 2020 20:36:55
User entered 'No (N)'	System	07 Dec 2020 20:36:55



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-12-07T15:36:51', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'cf2b2012-d2f8-46e3-8756-8ff27395e37a'	System	07 Dec 2020 20:36:55
User entered '07 Dec 2020 15:36:51'	System	07 Dec 2020 20:36:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[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 (1b5527e7a8ccc0c1)', Time: '2020-12-13T00:02:48', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5454e3e2-c1c2-434e-96ca-b165c0611cf1'	System	13 Dec 2020 05:03:18
User entered 'No (N)'	System	13 Dec 2020 05:03:18

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Have you been exposed to someone with 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 (1b5527e7a8ccc0c1)', Time: '2020-12-13T00:02:52', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5454e3e2-c1c2-434e-96ca-b165c0611cf1'	System	13 Dec 2020 05:03:18
User entered 'No (N)'	System	13 Dec 2020 05:03:18

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-12-13T00:02:55', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5454e3e2-c1c2-434e-96ca-b165c0611cf1' User entered '13 Dec 2020 00:02:55'	System	13 Dec 2020 05:03:18
	System	13 Dec 2020 05:03:18

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 20:17:55



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[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 (1b5527e7a8ccc0c1)', Time: '2020-12-21T11:45:52', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '0ccecdf1-9000-4b2d-ad7f-15394eb0f813'	System	21 Dec 2020 16:46:15
User entered 'No (N)'	System	21 Dec 2020 16:46:15

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Have you been exposed to someone with 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 (1b5527e7a8ccc0c1)', Time: '2020-12-21T11:46:06', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '0ccecdf1-9000-4b2d-ad7f-15394eb0f813'	System	21 Dec 2020 16:46:15
User entered 'No (N)'	System	21 Dec 2020 16:46:15

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-12-21T11:46:09', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '0ccecdf1-9000-4b2d-ad7f-15394eb0f813'	System	21 Dec 2020 16:46:15
User entered '21 Dec 2020 11:46:09'	System	21 Dec 2020 16:46:15

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 20:17:55



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[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 (1b5527e7a8ccc0c1)', Time: '2020-12-27T00:02:54', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'df2f7d5d-cd71-4034-86ac-318b623614ca'	System	27 Dec 2020 05:04:29
User entered 'No (N)'	System	27 Dec 2020 05:04:29

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Have you been exposed to someone with 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 (1b5527e7a8ccc0c1)', Time: '2020-12-27T00:04:20', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'df2f7d5d-cd71-4034-86ac-318b623614ca'	System	27 Dec 2020 05:04:29
User entered 'No (N)'	System	27 Dec 2020 05:04:29

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2020-12-27T00:04:25', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'df2f7d5d-cd71-4034-86ac-318b623614ca'	System	27 Dec 2020 05:04:29
User entered '27 Dec 2020 00:04:25'	System	27 Dec 2020 05:04:29

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[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 (1b5527e7a8ccc0c1)', Time: '2021-01-03T13:03:11', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '836271d6-483e-4127-a18f-c64897c382b3'	System	03 Jan 2021 18:03:23
User entered 'No (N)'	System	03 Jan 2021 18:03:23

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Have you been exposed to someone with 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 (1b5527e7a8ccc0c1)', Time: '2021-01-03T13:03:16', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '836271d6-483e-4127-a18f-c64897c382b3'	System	03 Jan 2021 18:03:23
User entered 'No (N)'	System	03 Jan 2021 18:03:23



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2021-01-03T13:03:19', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '836271d6-483e-4127-a18f-c64897c382b3'	System	03 Jan 2021 18:03:23
User entered '03 Jan 2021 13:03:19'	System	03 Jan 2021 18:03:23

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[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 (1b5527e7a8ccc0c1)', Time: '2021-01-11T21:35:46', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '123d01b3-1660-4e91-8c80-e6abf0e96f48'	System	12 Jan 2021 02:36:07
User entered 'No (N)'	System	12 Jan 2021 02:36:07

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Have you been exposed to someone with 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 (1b5527e7a8ccc0c1)', Time: '2021-01-11T21:36:00', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '123d01b3-1660-4e91-8c80-e6abf0e96f48'	System	12 Jan 2021 02:36:07
User entered 'No (N)'	System	12 Jan 2021 02:36:07

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2021-01-11T21:36:03', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '123d01b3-1660-4e91-8c80-e6abf0e96f48'	System	12 Jan 2021 02:36:07
User entered '11 Jan 2021 21:36:03'	System	12 Jan 2021 02:36:07

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 20:17:55



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[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 (1b5527e7a8ccc0c1)', Time: '2021-01-17T09:54:43', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'f994ee5c-a3db-48d4-8b6e-707cf956bb21'	System	17 Jan 2021 14:55:35
User entered 'Yes (Y)'	System	17 Jan 2021 14:55:35

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Have you been exposed to someone with 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 (1b5527e7a8ccc0c1)', Time: '2021-01-17T09:54:46', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'f994ee5c-a3db-48d4-8b6e-707cf956bb21'	System	17 Jan 2021 14:55:35
User entered 'No (N)'	System	17 Jan 2021 14:55:35

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[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 (1b5527e7a8ccc0c1)', Time: '2021-01-17T09:54:53', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'f994ee5c-a3db-48d4-8b6e-707cf956bb21'	System	17 Jan 2021 14:55:35
User entered 'No (N)'	System	17 Jan 2021 14:55:35

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[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 (1b5527e7a8ccc0c1)', Time: '2021-01-17T09:55:07', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'f994ee5c-a3db-48d4-8b6e-707cf956bb21'	System	17 Jan 2021 14:55:35
User entered 'Yes (Y)'	System	17 Jan 2021 14:55:35

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please 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 (1b5527e7a8ccc0c1)', Time: '2021-01-17T09:55:22', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'f994ee5c-a3db-48d4-8b6e-707cf956bb21'	System	17 Jan 2021 14:55:35
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Jan 2021 14:55:35

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2021-01-17T09:55:26', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'f994ee5c-a3db-48d4-8b6e-707cf956bb21'	System	17 Jan 2021 14:55:35
User entered '17 Jan 2021 09:55:26'	System	17 Jan 2021 14:55:35



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[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 (1b5527e7a8ccc0c1)', Time: '2021-01-28T12:05:28', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5f20afce-b162-4646-b0d5-4e14749c8cca'	System	28 Jan 2021 17:09:58
User entered 'Yes (Y)'	System	28 Jan 2021 17:09:58

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Have you been exposed to someone with 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 (1b5527e7a8ccc0c1)', Time: '2021-01-28T12:05:18', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5f20afce-b162-4646-b0d5-4e14749c8cca'	System	28 Jan 2021 17:09:58
User entered 'No (N)'	System	28 Jan 2021 17:09:58

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[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 (1b5527e7a8ccc0c1)', Time: '2021-01-28T12:05:34', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5f20afce-b162-4646-b0d5-4e14749c8cca'	System	28 Jan 2021 17:09:58
User entered 'No (N)'	System	28 Jan 2021 17:09:58

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[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 (1b5527e7a8ccc0c1)', Time: '2021-01-28T12:05:38', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5f20afce-b162-4646-b0d5-4e14749c8cca'	System	28 Jan 2021 17:09:58
User entered 'Yes (Y)'	System	28 Jan 2021 17:09:58

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Please 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 (1b5527e7a8ccc0c1)', Time: '2021-01-28T12:05:47', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5f20afce-b162-4646-b0d5-4e14749c8cca'	System	28 Jan 2021 17:09:58
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Jan 2021 17:09:58



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2021-01-28T12:05:52', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '5f20afce-b162-4646-b0d5-4e14749c8cca' User entered '28 Jan 2021 12:05:52'	System	28 Jan 2021 17:09:58
	System	28 Jan 2021 17:09:58

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[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 (1b5527e7a8ccc0c1)', Time: '2021-01-31T00:02:56', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '4096891b-d042-4d0d-8b59-74eab20c0c2f'	System	31 Jan 2021 05:04:02
User entered 'Yes (Y)'	System	31 Jan 2021 05:04:02

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Have you been exposed to someone with 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 (1b5527e7a8ccc0c1)', Time: '2021-01-31T00:03:31', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '4096891b-d042-4d0d-8b59-74eab20c0c2f'	System	31 Jan 2021 05:04:02
User entered 'No (N)'	System	31 Jan 2021 05:04:02

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[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 (1b5527e7a8ccc0c1)', Time: '2021-01-31T00:03:38', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '4096891b-d042-4d0d-8b59-74eab20c0c2f'	System	31 Jan 2021 05:04:02
User entered 'No (N)'	System	31 Jan 2021 05:04:02

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[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 (1b5527e7a8ccc0c1)', Time: '2021-01-31T00:03:44', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '4096891b-d042-4d0d-8b59-74eab20c0c2f'	System	31 Jan 2021 05:04:02
User entered 'Yes (Y)'	System	31 Jan 2021 05:04:02



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Please 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 (1b5527e7a8ccc0c1)', Time: '2021-01-31T00:03:47', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '4096891b-d042-4d0d-8b59-74eab20c0c2f'	System	31 Jan 2021 05:04:02
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	31 Jan 2021 05:04:02

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2021-01-31T00:03:50', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '4096891b-d042-4d0d-8b59-74eab20c0c2f' User entered '31 Jan 2021 00:03:50'	System	31 Jan 2021 05:04:02

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[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 (1b5527e7a8ccc0c1)', Time: '2021-02-10T20:02:53', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '024c5b9d-6913-4050-994a-5d601bb455ab'	System	11 Feb 2021 01:04:26
User entered 'Yes (Y)'	System	11 Feb 2021 01:04:26

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Have you been exposed to someone with 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 (1b5527e7a8ccc0c1)', Time: '2021-02-10T20:02:56', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '024c5b9d-6913-4050-994a-5d601bb455ab'	System	11 Feb 2021 01:04:26
User entered 'No (N)'	System	11 Feb 2021 01:04:26

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[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 (1b5527e7a8ccc0c1)', Time: '2021-02-10T20:02:59', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '024c5b9d-6913-4050-994a-5d601bb455ab'	System	11 Feb 2021 01:04:26
User entered 'No (N)'	System	11 Feb 2021 01:04:26



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[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 (1b5527e7a8ccc0c1)', Time: '2021-02-10T20:03:08', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '024c5b9d-6913-4050-994a-5d601bb455ab'	System	11 Feb 2021 01:04:26
User entered 'Yes (Y)'	System	11 Feb 2021 01:04:26

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Please 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 (1b5527e7a8ccc0c1)', Time: '2021-02-10T20:03:10', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '024c5b9d-6913-4050-994a-5d601bb455ab'	System	11 Feb 2021 01:04:26
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	11 Feb 2021 01:04:26

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2021-02-10T20:03:15', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '024c5b9d-6913-4050-994a-5d601bb455ab'	System	11 Feb 2021 01:04:26
User entered '10 Feb 2021 20:03:15'	System	11 Feb 2021 01:04:26

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[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 (1b5527e7a8ccc0c1)', Time: '2021-02-14T10:41:39', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '18f1faf5-2628-4178-a10e-092d4a5ca619'	System	14 Feb 2021 15:41:48
User entered 'No (N)'	System	14 Feb 2021 15:41:48

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Have you been exposed to someone with 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 (1b5527e7a8ccc0c1)', Time: '2021-02-14T10:41:42', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '18f1faf5-2628-4178-a10e-092d4a5ca619'	System	14 Feb 2021 15:41:48
User entered 'No (N)'	System	14 Feb 2021 15:41:48



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2021-02-14T10:41:44', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '18f1faf5-2628-4178-a10e-092d4a5ca619'	System	14 Feb 2021 15:41:48
User entered '14 Feb 2021 10:41:44'	System	14 Feb 2021 15:41:48

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[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 (1b5527e7a8ccc0c1)', Time: '2021-02-22T05:39:37', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '2e3d0d44-8d73-4387-913e-45bddb6d0c92'	System	22 Feb 2021 10:39:47
User entered 'No (N)'	System	22 Feb 2021 10:39:47

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Have you been exposed to someone with 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 (1b5527e7a8ccc0c1)', Time: '2021-02-22T05:39:40', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '2e3d0d44-8d73-4387-913e-45bddb6d0c92'	System	22 Feb 2021 10:39:47
User entered 'No (N)'	System	22 Feb 2021 10:39:47

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2021-02-22T05:39:43', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '2e3d0d44-8d73-4387-913e-45bddb6d0c92'	System	22 Feb 2021 10:39:47
User entered '22 Feb 2021 05:39:43'	System	22 Feb 2021 10:39:47

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 20:17:55



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[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 (1b5527e7a8ccc0c1)', Time: '2021-03-01T19:40:48', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'ee2a9d79-6f01-482d-98d5-5bf831fd80ea'	System	02 Mar 2021 00:41:02
User entered 'No (N)'	System	02 Mar 2021 00:41:02

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Have you been exposed to someone with 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 (1b5527e7a8ccc0c1)', Time: '2021-03-01T19:40:51', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'ee2a9d79-6f01-482d-98d5-5bf831fd80ea'	System	02 Mar 2021 00:41:02
User entered 'No (N)'	System	02 Mar 2021 00:41:02

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2021-03-01T19:40:54', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'ee2a9d79-6f01-482d-98d5-5bf831fd80ea'	System	02 Mar 2021 00:41:02
User entered '01 Mar 2021 19:40:54'	System	02 Mar 2021 00:41:02

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 20:17:55



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[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 (1b5527e7a8ccc0c1)', Time: '2021-03-07T00:19:15', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'c2deb122-b6a1-4414-94e2-86289dd3dd25'	System	07 Mar 2021 05:19:25
User entered 'No (N)'	System	07 Mar 2021 05:19:25

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Have you been exposed to someone with 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 (1b5527e7a8ccc0c1)', Time: '2021-03-07T00:19:19', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'c2deb122-b6a1-4414-94e2-86289dd3dd25'	System	07 Mar 2021 05:19:25
User entered 'No (N)'	System	07 Mar 2021 05:19:25

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2021-03-07T00:19:21', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'c2deb122-b6a1-4414-94e2-86289dd3dd25'	System	07 Mar 2021 05:19:25
User entered '07 Mar 2021 00:19:21'	System	07 Mar 2021 05:19:25

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[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 (1b5527e7a8ccc0c1)', Time: '2021-03-16T16:49:04', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '679a2b18-8193-4b09-bc31-97ac451bbcfb'	System	16 Mar 2021 20:49:15
User entered 'No (N)'	System	16 Mar 2021 20:49:15

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Have you been exposed to someone with 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 (1b5527e7a8ccc0c1)', Time: '2021-03-16T16:49:02', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '679a2b18-8193-4b09-bc31-97ac451bbcfb'	System	16 Mar 2021 20:49:15
User entered 'No (N)'	System	16 Mar 2021 20:49:15



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2021-03-16T16:49:08', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '679a2b18-8193-4b09-bc31-97ac451bbcfb' User entered '16 Mar 2021 16:49:08'	System	16 Mar 2021 20:49:15
	System	16 Mar 2021 20:49:15

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[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 (1b5527e7a8ccc0c1)', Time: '2021-03-23T05:54:23', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'ee791c36-d384-41c4-bf76-961520a6f0e3'	System	23 Mar 2021 09:54:35
User entered 'No (N)'	System	23 Mar 2021 09:54:35

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Have you been exposed to someone with 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 (1b5527e7a8ccc0c1)', Time: '2021-03-23T05:54:25', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'ee791c36-d384-41c4-bf76-961520a6f0e3'	System	23 Mar 2021 09:54:35
User entered 'No (N)'	System	23 Mar 2021 09:54:35

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2021-03-23T05:54:27', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'ee791c36-d384-41c4-bf76-961520a6f0e3'	System	23 Mar 2021 09:54:35
User entered '23 Mar 2021 05:54:27'	System	23 Mar 2021 09:54:35

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 20:17:55



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[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 (1b5527e7a8ccc0c1)', Time: '2021-03-28T05:25:47', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'f6be1c25-6201-477f-aae5-038d2e4007f8'	System	28 Mar 2021 09:25:58
User entered 'No (N)'	System	28 Mar 2021 09:25:58

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Have you been exposed to someone with 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 (1b5527e7a8ccc0c1)', Time: '2021-03-28T05:25:50', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'f6be1c25-6201-477f-aae5-038d2e4007f8'	System	28 Mar 2021 09:25:58
User entered 'No (N)'	System	28 Mar 2021 09:25:58

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2021-03-28T05:25:53', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'f6be1c25-6201-477f-aae5-038d2e4007f8' User entered '28 Mar 2021 05:25:53'	System	28 Mar 2021 09:25:58
	System	28 Mar 2021 09:25:58

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 20:17:55



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[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 (1b5527e7a8ccc0c1)', Time: '2021-04-12T05:28:31', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '68fbdd5a-911c-43bc-9d06-b9391e69b697'	System	12 Apr 2021 09:28:40
User entered 'No (N)'	System	12 Apr 2021 09:28:40

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Have you been exposed to someone with 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 (1b5527e7a8ccc0c1)', Time: '2021-04-12T05:28:34', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '68fbdd5a-911c-43bc-9d06-b9391e69b697'	System	12 Apr 2021 09:28:40
User entered 'No (N)'	System	12 Apr 2021 09:28:40

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2021-04-12T05:28:37', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '68fbdd5a-911c-43bc-9d06-b9391e69b697'	System	12 Apr 2021 09:28:40
User entered '12 Apr 2021 05:28:37'	System	12 Apr 2021 09:28:40

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 20:17:55



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[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 (1b5527e7a8ccc0c1)', Time: '2021-04-20T21:27:33', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '0ed6601e-1d79-4419-8068-e4fe890f4406'	System	21 Apr 2021 01:27:43
User entered 'No (N)'	System	21 Apr 2021 01:27:43

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Have you been exposed to someone with 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 (1b5527e7a8ccc0c1)', Time: '2021-04-20T21:27:35', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '0ed6601e-1d79-4419-8068-e4fe890f4406'	System	21 Apr 2021 01:27:43
User entered 'No (N)'	System	21 Apr 2021 01:27:43

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2021-04-20T21:27:38', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '0ed6601e-1d79-4419-8068-e4fe890f4406' User entered '20 Apr 2021 21:27:38'	System	21 Apr 2021 01:27:43

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[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 (1b5527e7a8ccc0c1)', Time: '2021-04-26T06:08:54', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '00624e75-b8a0-45ab-a253-58fd0b58710e'	System	26 Apr 2021 10:09:05
User entered 'No (N)'	System	26 Apr 2021 10:09:05



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

Have you been exposed to someone with 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 (1b5527e7a8ccc0c1)', Time: '2021-04-26T06:08:56', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '00624e75-b8a0-45ab-a253-58fd0b58710e'	System	26 Apr 2021 10:09:05
User entered 'No (N)'	System	26 Apr 2021 10:09:05

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2021-04-26T06:09:00', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '00624e75-b8a0-45ab-a253-58fd0b58710e'	System	26 Apr 2021 10:09:05
User entered '26 Apr 2021 06:09:00'	System	26 Apr 2021 10:09:05

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[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 (1b5527e7a8ccc0c1)', Time: '2021-05-03T18:47:55', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'fd0a2953-1cd9-4ba3-818c-bb481682d9c3'	System	03 May 2021 22:48:06
User entered 'No (N)'	System	03 May 2021 22:48:06

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Have you been exposed to someone with 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 (1b5527e7a8ccc0c1)', Time: '2021-05-03T18:47:58', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'fd0a2953-1cd9-4ba3-818c-bb481682d9c3'	System	03 May 2021 22:48:06
User entered 'No (N)'	System	03 May 2021 22:48:06

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2021-05-03T18:48:01', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: 'fd0a2953-1cd9-4ba3-818c-bb481682d9c3'	System	03 May 2021 22:48:06
User entered '03 May 2021 18:48:01'	System	03 May 2021 22:48:06



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 20:17:55



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 20:17:55



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 20:17:55



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 20:17:55



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 20:17:55



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 20:17:55



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 20:17:55



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 20:17:55



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 20:17:55



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 20:17:55



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 20:17:55



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 20:17:55



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 20:17:55



**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 20:17:55

**US3742148**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 20:17:55



**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 20:17:55



**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 20:17:55



**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 20:17:55



**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 20:17:55



**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 20:17:55



**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 20:17:55



**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 20:17:55



**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 20:17:55



**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 20:17:55



**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 20:17:55



**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 20:17:55



**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 20:17:55



**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 20:17:55



**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 20:17:55



**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '23 Oct 2022 00:01'	System	19 Nov 2020 20:17:55



**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '27 Oct 2022 23:59'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '30 Oct 2022 00:01'	System	19 Nov 2020 20:17:55

**US3742148**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:27:01**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:17:55
Amendment Manager: User entered '03 Nov 2022 23:59'	System	19 Nov 2020 20:17:55

US3742148

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:27:01

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 20:45:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2021-03-01T19:40:39', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '8dbb47ed-fbff-4e8e-83c7-3c94078177e3'	System	02 Mar 2021 00:40:51
User entered 'No (N)'	System	02 Mar 2021 00:40:51

**US3742148**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:27:01**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 20:45:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1b5527e7a8ccc0c1)', Time: '2021-03-01T19:40:42', User OID: 'PatientReportedOutcome (US3742148)', ODM File OID: '8dbb47ed-fbff-4e8e-83c7-3c94078177e3'	System	02 Mar 2021 00:40:51
User entered '01 Mar 2021 19:40:42'	System	02 Mar 2021 00:40:51

**US3742148**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:27:01**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered 'Yes (Y)'	Hassan Haji (b) (4)	20 Nov 2020 18:52:12

**US3742148**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:27:01**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered '20 Nov 2020'	Hassan Haji (b) (4)	20 Nov 2020 18:52:12



**US3742148**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:27:01**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered 'Contact Made (CONTACT MADE)'	Hassan Haji (b) (4)	20 Nov 2020 18:52:12

US3742148

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:01

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered empty.	Hassan Haji (b) (4)	20 Nov 2020 18:52:12

US3742148

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered 'Yes (Y)'	Hassan Haji (b) (4)	20 Nov 2020 18:52:17

**US3742148**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:27:01**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 10:59:43
User entered 'I'	System	20 Nov 2020 18:52:17

**US3742148**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:27:01**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:16:40
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Dec 2020 19:11:35

US3742148

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:01

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:16:40
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered '23 Dec 2020'	(b) (4) Sherry McCammon (b) (4)	23 Dec 2020 19:11:35

**US3742148**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:27:01**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:16:40
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	23 Dec 2020 19:11:35

US3742148

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:01

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:16:40
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered empty.	Sherry McCammon (b) (4)	23 Dec 2020 19:11:35



**US3742148**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:27:01**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:16:40
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	23 Dec 2020 19:11:41

**US3742148**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:27:01**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:16:40
User entered 'I'	System	23 Dec 2020 19:11:41

**US3742148**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:27:01**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:16:40
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	22 Jan 2021 18:16:51

**US3742148**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:27:01**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:16:40
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered '21 Jan 2021'	Sherry McCammon (b) (4)	22 Jan 2021 18:16:51

**US3742148**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:27:01**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:16:40
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	22 Jan 2021 18:16:51

US3742148

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:01

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:16:40
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered empty.	Sherry McCammon (b) (4)	22 Jan 2021 18:16:51

US3742148

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:16:40
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	22 Jan 2021 18:16:56

**US3742148**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:27:01**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:16:40
User entered 'I'	System	22 Jan 2021 18:16:56



**US3742148**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:27:01**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:25
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	01 Mar 2021 18:30:31

**US3742148**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:27:01**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:25
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
User entered '22 Feb 2021'	Sherry McCammon (b) (4)	01 Mar 2021 18:30:31

**US3742148**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:27:01**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:25
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
User entered 'Contact Made (CONTACT MADE)'	Sherry McCammon (b) (4)	01 Mar 2021 18:30:31

US3742148

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:01

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:25
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 18:30:31

**US3742148**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:27:01**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:25
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	01 Mar 2021 18:30:36

**US3742148**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:27:01**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:00:25
User entered 'I'	System	01 Mar 2021 18:30:36

US3742148

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:27:01

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 19:37:00

US3742148

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:27:01

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered '19 Mar 2021'	(b) (4), (b) (6)	19 Mar 2021 19:37:00



US3742148

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:27:01

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	19 Mar 2021 19:37:00

**US3742148**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:27:01**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:23
User entered 'VISIT4'	System	19 Mar 2021 19:37:00

US3742148

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 18:49:03

US3742148

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:49:03

**US3742148**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:27:01**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:49:03

**US3742148**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:27:01**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:23
User entered empty.	System	30 Mar 2021 18:49:03

US3742148

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:49:03

US3742148

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:49:03



US3742148

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:49:03

US3742148

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:49:03

**US3742148**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:27:01**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:23
User entered empty.	System	30 Mar 2021 18:49:03

US3742148

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:49:03

US3742148

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:23
User entered empty.	System	30 Mar 2021 18:49:03

US3742148

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:49:03

US3742148

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:23
User entered empty.	System	30 Mar 2021 18:49:03

US3742148

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:49:03



US3742148

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:23
User entered empty.	System	30 Mar 2021 18:49:03

US3742148

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:23

US3742148

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:27:01

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:23

US3742148

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:27:01

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	19 Mar 2021 19:37:12

US3742148

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:27:01

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 19:37:12

US3742148

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:27:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 19:38:19

US3742148

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:27:01

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered '19 Mar 2021'	(b) (4), (b) (6)	19 Mar 2021 19:38:19

US3742148

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:27:01

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Mar 2021 19:48:06
User entered '15:05' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 19:48:06
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Mar 2021 19:38:19
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 19:38:19



**US3742148**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:27:01**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:23
User entered '19 Mar 2021 15:05'	System	19 Mar 2021 19:48:06
User entered empty.	System	19 Mar 2021 19:38:19

US3742148

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:23
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 19:37:04

**US3742148**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:27:01**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:11:23
User entered '1'	System	19 Mar 2021 19:37:04

**US3742148**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:27:01**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:54:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:42:48

**US3742148**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:27:01**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:54:39
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:42:48

**US3742148**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:27:01**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:54:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:42:48

US3742148

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:27:01

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:54:39
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:42:48

US3742148

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:27:01

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	23 Apr 2021 17:54:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:42:54



**US3742148**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:27:01**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Apr 2021 15:42:54

**US3742148**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:27:01**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:51:32

**US3742148**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:27:01**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:51:32

US3742148

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:27:01

[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 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:51:32

**US3742148**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:27:01**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User entered 'UNBLND_DECIDE'	System	27 Jan 2021 20:51:32

US3742148

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:27:01

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Milagritos Tapia (b) (4)	13 Apr 2021 21:39:34
Signature has been broken.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:00:03
User entered '27 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 16:00:03
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered '6 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:52:31

**US3742148**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:27:01**

[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 21:38:11
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
User entered '0'	Kaitlin Mason (b) (4)	17 Mar 2021 18:58:20
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:56:21

**US3742148**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:27:01**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:52:31



**US3742148**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:27:01**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4)	
	Kaitlin Mason (b) (4)	17 Mar 2021 18:58:20
	(b) (4)	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:56:21

US3742148

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:27:01

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:52:31

US3742148

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:27:01

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered empty.	(b) (4)	27 Jan 2021 20:52:31
	(b) (4), (b) (6)	

**US3742148**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:27:01**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:52:31

US3742148

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:27:01

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered empty.	(b) (4)	27 Jan 2021 20:52:31
	(b) (4), (b) (6)	

US3742148

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:27:01

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered empty.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:52:31

**US3742148**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:27:01**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User entered empty.	System	27 Jan 2021 20:52:31

**US3742148**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:27:01**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User entered empty.	System	27 Jan 2021 20:52:31



US3742148

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:27:01

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:51:51

US3742148

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:27:01

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:51:51

**US3742148**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:27:01**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered '09:23'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:51:51

**US3742148**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:27:01**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User entered '27 Jan 2021 09:23'	System	27 Jan 2021 20:51:51

**US3742148**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:27:01**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:52:09

**US3742148**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:27:01**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:52:09

**US3742148**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:27:01**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered '09:27'	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:52:09

**US3742148**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:27:01**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:38:11
User entered '27 Jan 2021 09:27'	System	27 Jan 2021 20:52:09



US3742148

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:27:01

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:16
User closed query 'Per DM CLR: Per Safety Follow-up Diary Day 145, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 10:06:45
User closed query 'Per DM CLR: Per Day 166 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 12:42:44
Query 'Per DM CLR: Per Safety Follow-up Diary Day 145, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'no AE needed. participant contacted ob/gyn to make an appointment. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 15:21:24

US3742148

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:27:01

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Per Day 166 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'participant did see her healthcare provider for a follow check up. no procedures done.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 15:15:49
User opened query 'Per DM CLR: Per Safety Follow-up Diary Day 145, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	03 Apr 2021 20:54:20
User opened query 'Per DM CLR: Per Day 166 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 06:08:51
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:40
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	04 Feb 2021 16:08:22

**US3742148**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:27:01**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 19:12:22
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 17:19:28
User entered	System	04 Feb 2021 17:19:21
'USA-US127-2021-mRNA-1273-P301000010'		
User entered 'New'	(b) (4), (b) (6)	04 Feb 2021 17:19:21

US3742148

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:01

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 19:12:22
User coded data point as SOC: Pregnancy, puerperium and perinatal conditions, HLGT: Abortions and stillbirth, HLT: Abortions spontaneous, PT: Abortion spontaneous, LLT: Spontaneous abortion - version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 16:11:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Feb 2021 16:11:46
Data point term sent to Coder	System	04 Feb 2021 16:11:04
User entered 'spontaneous abortion'	Sherry McCammon (b) (4)	04 Feb 2021 16:10:14
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:27:01**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:12:22
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	04 Feb 2021 16:10:14

**US3742148**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:27:01**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:12:22
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	04 Feb 2021 16:10:14

**US3742148**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:27:01**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:12:22
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	04 Feb 2021 16:10:14

US3742148

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 19:12:22
User entered '29 Jan 2021'	Sherry McCammon (b) (4)	04 Feb 2021 16:10:14
	(b) (4)	



**US3742148**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:27:01**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:12:22
User entered empty.	Sherry McCammon (b) (4) (b) (4)	04 Feb 2021 16:10:14

**US3742148**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:27:01**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 16:10:14

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:27:01**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:12:22
User entered 'No (N)'	Sherry McCammon (b) (4) (b) (4)	04 Feb 2021 16:10:14

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:27:01**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:12:22
User entered '29 Jan 2021'	Sherry McCammon (b) (4) (b) (4)	04 Feb 2021 16:10:14

**US3742148**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:27:01**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:12:22
User entered empty.	Sherry McCammon (b) (4) (b) (4)	04 Feb 2021 16:10:14

**US3742148**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:27:01**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 16:10:14

**US3742148**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:27:01**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:12:22
User entered 'Grade 3/Severe (Grade 3/Severe)'	Sherry McCammon (b) (4) (b) (4)	04 Feb 2021 16:10:14

US3742148

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
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).	(b) (4) System	25 Feb 2021 14:10:32
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	25 Feb 2021 14:08:58
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:12:22
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	04 Feb 2021 16:14:06
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	04 Feb 2021 16:10:14
User entered 'Yes (Y)'	Sherry McCammon (b) (4) (b) (4)	04 Feb 2021 16:10:14



**US3742148**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:27:01**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 19:12:22
User entered '0'	Sherry McCammon (b) (4)	04 Feb 2021 16:10:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:01

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:08:58
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 14:08:58
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:12:22
User entered '1' reason for change: Data Entry Error	Sherry McCammon (b) (4)	04 Feb 2021 16:14:06
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	04 Feb 2021 16:10:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:01

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 19:12:22
User entered '0'	Sherry McCammon (b) (4)	04 Feb 2021 16:10:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:12:22
User entered empty.	Sherry McCammon (b) (4) (b) (4)	04 Feb 2021 16:10:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:01

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:12:22
User entered empty.	Sherry McCammon (b) (4) (b) (4)	04 Feb 2021 16:10:14

**US3742148**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:27:01**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:12:22
User entered empty.	Sherry McCammon (b) (4) (b) (4)	04 Feb 2021 16:10:14

**US3742148**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:27:01**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:12:22
User entered empty.	Sherry McCammon (b) (4) (b) (4)	04 Feb 2021 16:10:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:01

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 19:12:22
User entered '0'	Sherry McCammon (b) (4)	04 Feb 2021 16:10:14
	(b) (4)	



**US3742148**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:27:01**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 19:12:22
User entered '0'	Sherry McCammon (b) (4)	04 Feb 2021 16:10:14
	(b) (4)	

**US3742148**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:27:01**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 14:10:32
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Feb 2021 14:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:12:22
User entered '0'	Sherry McCammon (b) (4)	04 Feb 2021 16:10:14
	(b) (4)	

US3742148

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:12:22
User entered 'Not Related (NOT RELATED)'	Sherry McCammon (b) (4) (b) (4)	04 Feb 2021 16:10:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:12:22
User entered 'Not Related (NOT RELATED)'	Sherry McCammon (b) (4) (b) (4)	04 Feb 2021 16:10:14

**US3742148**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:27:01**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 19:12:22
User entered 'Not Applicable (NOT APPLICABLE)'	Sherry McCammon (b) (4) (b) (4)	04 Feb 2021 16:10:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:01

None

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 11:58:19
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' answered with 'participant suffered miscarriage' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Feb 2021 14:07:44
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:12:22
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 08:33:18
User entered 'I'	Sherry McCammon (b) (4) (b) (4)	04 Feb 2021 16:10:14

**US3742148**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:27:01**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 19:12:22
User entered '0'	Sherry McCammon (b) (4)	04 Feb 2021 16:10:14
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:27:01**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 19:12:22
User entered '0'	Sherry McCammon (b) (4)	04 Feb 2021 16:10:14
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:27:01**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 19:12:22
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Sherry McCammon (b) (4)	04 Feb 2021 16:10:14
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:27:01**

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Feb 2021 19:12:22
User entered empty.	Sherry McCammon (b) (4)	04 Feb 2021 16:10:14
	(b) (4)	

US3742148

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:27:01

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
User closed query 'PV Query: There is no clinical information in the source documentation about the spontaneous abortion being life-threatening to the subject. Please provide supporting documentation or consider removing life-threatening serious criterion.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 15:45:24
Query 'PV Query: There is no clinical information in the source documentation about the spontaneous abortion being life-threatening to the subject. Please provide supporting documentation or consider removing life-threatening serious criterion.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 14:10:39
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:12:22
User opened query 'PV Query: There is no clinical information in the source documentation about the spontaneous abortion being life-threatening to the subject. Please provide supporting documentation or consider removing life-threatening serious criterion.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 20:49:38
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	04 Feb 2021 16:14:06
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	04 Feb 2021 16:14:06
User entered 'day 159 alert follow-up yielded that theSherry McCammon (b) (4) volunteer had a miscarriage on 29JAN2021. It was confirmed with her OB/GYN on 29JAN2021. participant reported she was 6 weeks pregnant.' reason for change: Data Entry Error	(b) (4)	04 Feb 2021 16:14:06
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	04 Feb 2021 16:10:14
User entered empty.	Sherry McCammon (b) (4) (b) (4)	04 Feb 2021 16:10:14

**US3742148**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:27:01**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Feb 2021 16:10:14

**US3742148**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:27:01**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Feb 2021 16:10:14

**US3742148**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:27:01**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:40:02

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:27:01

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:40:02
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: Urinary tract infection - version MedDRA\\23.0.	Coder Import (b) (4)	01 Mar 2021 18:34:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Mar 2021 18:34:57
Data point term sent to Coder	System	01 Mar 2021 18:33:37
User entered 'urinary tract infection'	Sherry McCammon (b) (4)	01 Mar 2021 18:33:04

US3742148

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:27:01

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:40:02
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Mar 2021 17:08:55
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 17:08:55
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Mar 2021 18:33:04
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 18:33:04
	(b) (4)	



**US3742148**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:27:01**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:40:02
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
User entered 'No (N)'	(b) (4)	
	Sherry McCammon (b) (4)	01 Mar 2021 18:33:04
	(b) (4)	

**US3742148**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:27:01**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:40:02
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	01 Mar 2021 18:33:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:27:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:40:02
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
User entered '21 Feb 2021'	(b) (4)	
	Sherry McCammon (b) (4)	01 Mar 2021 18:33:04
	(b) (4)	

**US3742148**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:27:01**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:40:02
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 18:33:04

**US3742148**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:27:01**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:40:02
User entered empty.	System	01 Mar 2021 18:33:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:27:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:40:02
User signature succeeded.	Milagritos Tapia (b) (4)	25 Mar 2021 17:56:37
Signature has been broken.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:35:27
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	19 Mar 2021 19:35:27
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
User entered 'Yes (Y)'	(b) (4) Sherry McCammon (b) (4)	01 Mar 2021 18:33:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:27:01

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:40:02
User signature succeeded.	Milagritos Tapia (b) (4)	25 Mar 2021 17:56:37
Signature has been broken.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:35:27
User entered '28 Feb 2021' reason for change: New Information	(b) (4), (b) (6)	19 Mar 2021 19:35:27
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
User entered empty.	(b) (4) Sherry McCammon (b) (4)	01 Mar 2021 18:33:04

**US3742148**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:27:01**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:40:02
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 18:33:04



**US3742148**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:27:01**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:40:02
User entered empty.	System	01 Mar 2021 18:33:04

**US3742148**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:27:01**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:40:02
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	
	Sherry McCammon (b) (4)	01 Mar 2021 18:33:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:27:01

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:40:02
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Mar 2021 17:08:55
User entered 'No (N)' reason for change: Data Entry Error	System	02 Mar 2021 17:08:55
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	02 Mar 2021 17:08:55
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 18:33:04
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:27:01**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:40:02
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
User entered '0'	Sherry McCammon (b) (4)	01 Mar 2021 18:33:04

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:27:01**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:40:02
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
User entered '0'	Sherry McCammon (b) (4)	01 Mar 2021 18:33:04

**US3742148**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:27:01**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:40:02
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
User entered '0'	Sherry McCammon (b) (4)	01 Mar 2021 18:33:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:27:01

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:40:02
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 18:33:04

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:27:01**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:40:02
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 18:33:04



**US3742148**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:27:01**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:40:02
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 18:33:04

**US3742148**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:27:01**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:40:02
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 18:33:04

**US3742148**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:27:01**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:40:02
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
User entered '0'	Sherry McCammon (b) (4)	01 Mar 2021 18:33:04

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:27:01**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:40:02
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
User entered '0'	(b) (4)	
	Sherry McCammon (b) (4)	01 Mar 2021 18:33:04
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:27:01**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:40:02
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
User entered '0'	Sherry McCammon (b) (4)	01 Mar 2021 18:33:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:27:01

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:40:02
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Mar 2021 17:08:55
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	02 Mar 2021 17:08:55
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	02 Mar 2021 17:08:55
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	01 Mar 2021 18:33:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:27:01

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:40:02
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Mar 2021 17:08:55
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	System	02 Mar 2021 17:08:55
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	02 Mar 2021 17:08:55
User entered empty.	(b) (4)	
	System	01 Mar 2021 18:33:04
	Sherry McCammon (b) (4)	01 Mar 2021 18:33:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:27:01

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:40:02
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Mar 2021 17:08:55
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	System	02 Mar 2021 17:08:55
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	02 Mar 2021 17:08:55
User entered empty.	(b) (4)	
	Sherry McCammon (b) (4)	01 Mar 2021 18:33:04
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:27:01**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:40:02
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
User entered '0'	Sherry McCammon (b) (4)	01 Mar 2021 18:33:04

**US3742148**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:27:01**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:40:02
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
User entered 'I'	Sherry McCammon (b) (4)	01 Mar 2021 18:33:04

**US3742148**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:27:01**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:40:02
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
User entered '0'	Sherry McCammon (b) (4)	01 Mar 2021 18:33:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:27:01

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:40:02
User signature succeeded.	Milagritos Tapia (b) (4)	25 Mar 2021 17:56:37
Signature has been broken.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:35:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	19 Mar 2021 19:35:27
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Sherry McCammon (b) (4)	01 Mar 2021 18:33:04

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:27:01**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:40:02
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
User entered empty.	(b) (4) Sherry McCammon (b) (4)	01 Mar 2021 18:33:04

**US3742148**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:27:01**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:40:02
User signature succeeded.	Milagritos Tapia (b) (4)	14 Mar 2021 21:27:06
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 18:33:04

**US3742148**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:27:01**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:40:02
User entered '0'	System	02 Mar 2021 17:08:55

**US3742148**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:27:01**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:40:02
User entered 'I'	System	02 Mar 2021 17:08:55



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:27:01**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:40:02

US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:27:01

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:31:16
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
User closed query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site Day 3, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 08:53:46
Query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site Day 3, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'concomitant therapeutic effect from medications listed ' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	20 Feb 2021 19:48:03
User opened query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site Day 3, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 13:44:52
User entered 'Yes (Y)' reason for change: New Information	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 19:11:15
User entered 'No (N)'	Kaitlin Mason (b) (4) (b) (4)	11 Sep 2020 20:06:51

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:27:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 19:13:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 19:13:50
Data point term sent to Coder	System	21 Sep 2020 19:12:29
User entered 'TYLENOL'	Kaitlin Mason (b) (4)	21 Sep 2020 19:12:16

US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:27:01

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered 'No (N)'	Kaitlin Mason (b) (4)	21 Sep 2020 19:12:16

US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:27:01

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Dec 2020 14:56:14
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' answered with 'REACTOGENICITY - DOES NOT MEET CRITERIA TO REPORT AS AE' (Site from DM).	Kaitlin Mason (b) (4) (b) (4)	27 Oct 2020 16:53:17

US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:27:01

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 06:32:06
User entered 'HEADACHE'	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 19:12:16

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:27:01**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered '325'	Kaitlin Mason (b) (4)	21 Sep 2020 19:12:16

US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:27:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered 'mg (mg)'	(b) (4) Kaitlin Mason (b) (4)	21 Sep 2020 19:12:16



US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:27:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered empty.	(b) (4) Kaitlin Mason (b) (4)	21 Sep 2020 19:12:16

US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:27:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered 'three times daily (TID)'	Kaitlin Mason (b) (4)	21 Sep 2020 19:12:16

US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:27:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered empty.	(b) (4) Kaitlin Mason (b) (4)	21 Sep 2020 19:12:16

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:27:01**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered 'Oral (ORAL)'	Kaitlin Mason (b) (4)	21 Sep 2020 19:12:16

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:27:01**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered empty.	(b) (4) Kaitlin Mason (b) (4)	21 Sep 2020 19:12:16

US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:27:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User closed query 'Per CDM: Please review start date of this medication as it does not correspond with Diary Dose 1 - Temperature Day CRF. Kindly reconcile as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 14:31:47
Query 'Per CDM: Please review start date of this medication as it does not correspond with Diary Dose 1 - Temperature Day CRF. Kindly reconcile as appropriate.' answered with 'CORRECTED' (Site from DM).	Sherry McCammon (b) (4) (b) (4)	24 Sep 2020 14:05:55
User entered '30 Aug 2020' reason for change: Data Entry Error	Sherry McCammon (b) (4) (b) (4)	24 Sep 2020 14:05:42
User opened query 'Per CDM: Please review start date of this medication as it does not correspond with Diary Dose 1 - Temperature Day CRF. Kindly reconcile as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 13:18:21
Query 'Per CDM: Please review start date of this medication as it does not correspond with Diary Dose - Temperature Day CRF. Kindly reconcile as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 13:18:07
User opened query 'Per CDM: Please review start date of this medication as it does not correspond with Diary Dose - Temperature Day CRF. Kindly reconcile as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 13:17:46
User entered '31 Aug 2020'	Kaitlin Mason (b) (4) (b) (4)	21 Sep 2020 19:12:16

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:27:01**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered '0'	Kaitlin Mason (b) (4)	21 Sep 2020 19:12:16

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:27:01**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered 'No (N)'	Kaitlin Mason (b) (4)	21 Sep 2020 19:12:16



US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:27:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered '01 Sep 2020'	Kaitlin Mason (b) (4)	21 Sep 2020 19:12:16

US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:27:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:30
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered 'No (N)'	Kaitlin Mason (b) (4)	21 Sep 2020 19:12:16

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:27:01**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:30
User entered '3'	System	21 Sep 2020 19:12:16

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:27:01**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:30
User entered '1'	System	21 Sep 2020 19:12:16

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:27:01**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:30
User entered '804 (804)'	System	21 Sep 2020 19:12:16

US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:27:01

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
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 19:17:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 19:17:58
Data point term sent to Coder	System	24 Nov 2020 19:16:50
User entered 'INFLUENZA VACCINE'	Sherry McCammon (b) (4)	24 Nov 2020 19:16:08

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:27:01**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	24 Nov 2020 19:16:08

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:27:01**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered 'FLU PROPHYLAXIS'	Sherry McCammon (b) (4)	24 Nov 2020 19:16:08



**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:27:01**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered '0.5'	Sherry McCammon (b) (4)	24 Nov 2020 19:16:08

US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:27:01

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered 'mL (mL)'	(b) (4) Sherry McCammon (b) (4)	24 Nov 2020 19:16:08

US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:27:01

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered empty.	Sherry McCammon (b) (4)	24 Nov 2020 19:16:08

US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:27:01

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered 'once (ONCE)'	(b) (4) Sherry McCammon (b) (4)	24 Nov 2020 19:16:08

US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:27:01

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered empty.	Sherry McCammon (b) (4)	24 Nov 2020 19:16:08

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:27:01**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Sherry McCammon (b) (4)	24 Nov 2020 19:16:08

US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:27:01

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered empty.	Sherry McCammon (b) (4)	24 Nov 2020 19:16:08

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:27:01**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered '20 Nov 2020'	Sherry McCammon (b) (4)	24 Nov 2020 19:16:08



**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:27:01**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered '0'	Sherry McCammon (b) (4)	24 Nov 2020 19:16:08

US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:27:01

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered 'No (N)'	(b) (4) Sherry McCammon (b) (4)	24 Nov 2020 19:16:08

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:27:01**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered '20 Nov 2020'	Sherry McCammon (b) (4)	24 Nov 2020 19:16:08

US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:27:01

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:32
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered 'No (N)'	Sherry McCammon (b) (4)	24 Nov 2020 19:16:08

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:27:01**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:32
User entered empty.	System	24 Nov 2020 19:16:08

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:27:01**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:32
User entered empty.	System	24 Nov 2020 19:16:08

US3742148

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:27:01**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:53:32
User entered empty.	System	24 Nov 2020 19:16:08

US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:27:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: NITROFURAN DERIVATIVES, PRODUCT: NITROFURANTOIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Mar 2021 13:16:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 13:16:42
Data point term sent to Coder	System	01 Mar 2021 18:40:47
User entered 'nitrofuantoin'	Sherry McCammon (b) (4) (b) (4)	01 Mar 2021 18:39:54



US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:27:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	01 Mar 2021 18:39:54
	(b) (4)	

US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:27:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered 'urinary tract infection'	Sherry McCammon (b) (4)	01 Mar 2021 18:39:54
	(b) (4)	

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:27:01**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered '100'	Sherry McCammon (b) (4)	01 Mar 2021 18:39:54
	(b) (4)	

US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:27:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered 'mg (mg)'	Sherry McCammon (b) (4)	01 Mar 2021 18:39:54
	(b) (4)	

US3742148

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:27:01**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 18:39:54
	(b) (4)	

US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:27:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered 'twice daily (BID)'	Sherry McCammon (b) (4)	01 Mar 2021 18:39:54
	(b) (4)	

US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:27:01

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 18:39:54
	(b) (4)	

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:27:01**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4)	01 Mar 2021 18:39:54
	(b) (4)	



US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:27:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 18:39:54
	(b) (4)	

US3742148

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:27:01**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered '21 Feb 2021'	Sherry McCammon (b) (4)	01 Mar 2021 18:39:54
	(b) (4)	

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:27:01**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	01 Mar 2021 18:39:54
	(b) (4)	

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:27:01**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	01 Mar 2021 18:39:54
	(b) (4)	

US3742148

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:27:01**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	01 Mar 2021 18:39:54
	(b) (4)	

US3742148

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:27:01**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	01 Mar 2021 18:39:54
	(b) (4)	

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:27:01**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Mar 2021 18:39:54

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:27:01**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Mar 2021 18:39:54



**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:27:01**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Mar 2021 18:39:54

US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:27:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ANTIADRENERGIC AGENTS, PERIPHERALLY ACTING, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: PRAZOSIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Mar 2021 13:18:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Mar 2021 13:18:44
Data point term sent to Coder	System	22 Mar 2021 13:18:04
User entered 'prazosin'	Sherry McCammon (b) (4) (b) (4)	22 Mar 2021 13:17:52

US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:27:01

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	22 Mar 2021 13:17:52
	(b) (4)	

US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:27:01

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
User entered 'post traumatic stress disorder'	(b) (4) Sherry McCammon (b) (4)	22 Mar 2021 13:17:52

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:27:01**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Sherry McCammon (b) (4)	22 Mar 2021 13:18:15
	(b) (4)	
User entered '10'	Sherry McCammon (b) (4)	22 Mar 2021 13:17:52
	(b) (4)	

US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:27:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered 'mg (mg)'	Sherry McCammon (b) (4)	22 Mar 2021 13:17:52
	(b) (4)	

US3742148

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:27:01**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	22 Mar 2021 13:17:52
	(b) (4)	

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:27:01**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered 'once daily (QD)'	Sherry McCammon (b) (4)	22 Mar 2021 13:17:52
	(b) (4)	



US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:27:01

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	22 Mar 2021 13:17:52
	(b) (4)	

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:27:01**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4)	22 Mar 2021 13:17:52
	(b) (4)	

US3742148

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:27:01**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	22 Mar 2021 13:17:52
	(b) (4)	

US3742148

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:27:01**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered '7 Mar 2021'	Sherry McCammon (b) (4)	22 Mar 2021 13:17:52
	(b) (4)	

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:27:01**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	22 Mar 2021 13:17:52
	(b) (4)	

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:27:01**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	22 Mar 2021 13:17:52
	(b) (4)	

US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:27:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	22 Mar 2021 13:17:52
	(b) (4)	

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:27:01**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	22 Mar 2021 13:17:52
	(b) (4)	



**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:27:01**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Mar 2021 13:17:52

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:27:01**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Mar 2021 13:17:52

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:27:01**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Mar 2021 13:17:52

US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:27:01

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: ESCITALOPRAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	22 Mar 2021 13:19:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Mar 2021 13:19:44
Data point term sent to Coder	System	22 Mar 2021 13:19:05
User entered 'escitalopram'	Sherry McCammon (b) (4) (b) (4)	22 Mar 2021 13:18:58

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:27:01**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	22 Mar 2021 13:18:58
	(b) (4)	

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:27:01**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered 'depression'	Sherry McCammon (b) (4)	22 Mar 2021 13:18:58
	(b) (4)	

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:27:01**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered '10'	Sherry McCammon (b) (4)	22 Mar 2021 13:18:58
	(b) (4)	

US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:27:01

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered 'mg (mg)'	Sherry McCammon (b) (4)	22 Mar 2021 13:18:58
	(b) (4)	



US3742148

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:27:01**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	22 Mar 2021 13:18:58
	(b) (4)	

US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:27:01

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered 'once daily (QD)'	Sherry McCammon (b) (4)	22 Mar 2021 13:18:58
	(b) (4)	

US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:27:01

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	22 Mar 2021 13:18:58
	(b) (4)	

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:27:01**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered 'Oral (ORAL)'	Sherry McCammon (b) (4)	22 Mar 2021 13:18:58
	(b) (4)	

US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:27:01

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	22 Mar 2021 13:18:58
	(b) (4)	

US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:27:01

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered '7 Mar 2021'	Sherry McCammon (b) (4)	22 Mar 2021 13:18:58
	(b) (4)	

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:27:01**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered '0'	Sherry McCammon (b) (4)	22 Mar 2021 13:18:58
	(b) (4)	

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:27:01**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered 'Yes (Y)'	Sherry McCammon (b) (4)	22 Mar 2021 13:18:58
	(b) (4)	



US3742148

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:27:01

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered empty.	Sherry McCammon (b) (4)	22 Mar 2021 13:18:58
	(b) (4)	

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:27:01**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	22 Mar 2021 13:18:58
	(b) (4)	

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:27:01**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Mar 2021 13:18:58

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:27:01**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Mar 2021 13:18:58

**US3742148**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:27:01**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Mar 2021 13:18:58

US3742148

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 10 Jun 2021 09:27:01**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
User entered 'No (N)'	Sherry McCammon (b) (4)	01 Mar 2021 18:31:39
	(b) (4)	

**US3742148**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:27:01**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered 'USA-US127-2021-MRNA-1273-P301000010'	System	04 Feb 2021 17:19:21

US3742148

Folder: SAE USA-US127-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:01

Serious

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:27:15
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 17:03:33
User entered 'Yes (Y)'	System	25 Feb 2021 14:10:32
Un-reviewed for Safety.	System	25 Feb 2021 14:08:58
DataPoint Un-verified.	System	25 Feb 2021 14:08:58
Signature has been broken.	System	25 Feb 2021 14:08:58
User entered 'No (N)'	System	25 Feb 2021 14:08:58
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered 'Yes (Y)'	System	04 Feb 2021 17:19:21



**US3742148**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:27:01**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered 'No (N)'	System	04 Feb 2021 17:19:21

US3742148

Folder: SAE USA-US127-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:01

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:27:15
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 17:03:33
Un-reviewed for Safety.	System	25 Feb 2021 14:08:58
Signature has been broken.	System	25 Feb 2021 14:08:58
User entered 'No (N)'	System	25 Feb 2021 14:08:58
DataPoint Un-verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:24
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered 'Yes (Y)'	System	04 Feb 2021 17:19:21

**US3742148**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:27:01**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered 'No (N)'	System	04 Feb 2021 17:19:21

**US3742148**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:27:01**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered 'No (N)'	System	04 Feb 2021 17:19:21

**US3742148**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:27:01**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered 'No (N)'	System	04 Feb 2021 17:19:21

**US3742148**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:27:01**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:27:15
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 17:03:33
Un-reviewed for Safety.	System	25 Feb 2021 14:10:32
DataPoint Un-verified.	System	25 Feb 2021 14:10:32
Signature has been broken.	System	25 Feb 2021 14:10:32
User entered 'Yes (Y)'	System	25 Feb 2021 14:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered 'No (N)'	System	04 Feb 2021 17:19:21

**US3742148**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:27:01**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered 'Karen'	System	04 Feb 2021 17:19:21

US3742148

Folder: SAE USA-US127-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:01

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered 'Kotloff'	System	04 Feb 2021 17:19:21



**US3742148**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:27:01**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered '685 W. Baltimore Street, HSF 480'	System	04 Feb 2021 17:19:21

**US3742148**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:27:01**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered 'Baltimore'	System	04 Feb 2021 17:19:21

**US3742148**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:27:01**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered '21201'	System	04 Feb 2021 17:19:21

**US3742148**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:27:01**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 17:03:33
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered 'US'	(b) (4) System	04 Feb 2021 17:19:53

**US3742148**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:27:01**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	26 Feb 2021 17:03:50
User entered '2'	System	26 Feb 2021 17:03:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
	(b) (4)	
User entered '1'	System	04 Feb 2021 17:19:53

**US3742148**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:27:01**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered 'USA-US127-2021-MRNA-1273-P301000010'	System	04 Feb 2021 17:19:21

US3742148

Folder: SAE USA-US127-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:01

Serious

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:27:15
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 17:03:33
User entered 'Yes (Y)'	System	25 Feb 2021 14:10:32
Un-reviewed for Safety.	System	25 Feb 2021 14:08:58
DataPoint Un-verified.	System	25 Feb 2021 14:08:58
Signature has been broken.	System	25 Feb 2021 14:08:58
User entered 'No (N)'	System	25 Feb 2021 14:08:58
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered 'Yes (Y)'	System	04 Feb 2021 17:19:21

**US3742148**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:27:01**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered 'No (N)'	System	04 Feb 2021 17:19:21



US3742148

Folder: SAE USA-US127-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:01

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:27:15
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 17:03:33
Un-reviewed for Safety.	System	25 Feb 2021 14:08:58
Signature has been broken.	System	25 Feb 2021 14:08:58
User entered 'No (N)'	System	25 Feb 2021 14:08:58
DataPoint Un-verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:24
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered 'Yes (Y)'	System	04 Feb 2021 17:19:21

**US3742148**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:27:01**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered 'No (N)'	System	04 Feb 2021 17:19:21

**US3742148**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:27:01**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered 'No (N)'	System	04 Feb 2021 17:19:21

**US3742148**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:27:01**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered 'No (N)'	System	04 Feb 2021 17:19:21

US3742148

Folder: SAE USA-US127-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:01

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:27:15
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 17:03:33
Un-reviewed for Safety.	System	25 Feb 2021 14:10:32
DataPoint Un-verified.	System	25 Feb 2021 14:10:32
Signature has been broken.	System	25 Feb 2021 14:10:32
User entered 'Yes (Y)'	System	25 Feb 2021 14:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered 'No (N)'	System	04 Feb 2021 17:19:21

**US3742148**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:27:01**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered 'Karen'	System	04 Feb 2021 17:19:21

**US3742148**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:27:01**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered 'Kotloff'	System	04 Feb 2021 17:19:21

**US3742148**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:27:01**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered '685 W. Baltimore Street, HSF 480'	System	04 Feb 2021 17:19:21



**US3742148**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:27:01**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered 'Baltimore'	System	04 Feb 2021 17:19:21

**US3742148**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:27:01**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered '21201'	System	04 Feb 2021 17:19:21

**US3742148**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:27:01**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 17:03:33
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered 'US'	(b) (4) System	04 Feb 2021 17:19:53

**US3742148**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:27:01**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	26 Feb 2021 17:03:50
User entered '2'	System	26 Feb 2021 17:03:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
	(b) (4)	
User entered '1'	System	04 Feb 2021 17:19:53

**US3742148**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000010**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:27:01**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered '04/Feb/2021 17:19'	(b) (4) System	04 Feb 2021 17:19:53

US3742148

Folder: SAE USA-US127-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:27:01

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 17:03:33
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered 'I'	(b) (4), (b) (6)	04 Feb 2021 17:19:53

**US3742148**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:27:01**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered 'USA-US127-2021-MRNA-1273-P301000010'	System	04 Feb 2021 17:19:21

US3742148

Folder: SAE USA-US127-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:01

Serious

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:27:15
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 17:03:33
User entered 'Yes (Y)'	System	25 Feb 2021 14:10:32
Un-reviewed for Safety.	System	25 Feb 2021 14:08:58
DataPoint Un-verified.	System	25 Feb 2021 14:08:58
Signature has been broken.	System	25 Feb 2021 14:08:58
User entered 'No (N)'	System	25 Feb 2021 14:08:58
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered 'Yes (Y)'	System	04 Feb 2021 17:19:21



**US3742148**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:27:01**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered 'No (N)'	System	04 Feb 2021 17:19:21

US3742148

Folder: SAE USA-US127-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:01

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:27:15
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 17:03:33
Un-reviewed for Safety.	System	25 Feb 2021 14:08:58
Signature has been broken.	System	25 Feb 2021 14:08:58
User entered 'No (N)'	System	25 Feb 2021 14:08:58
DataPoint Un-verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:24
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered 'Yes (Y)'	System	04 Feb 2021 17:19:21

**US3742148**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:27:01**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered 'No (N)'	System	04 Feb 2021 17:19:21

**US3742148**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:27:01**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered 'No (N)'	System	04 Feb 2021 17:19:21

**US3742148**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:27:01**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered 'No (N)'	System	04 Feb 2021 17:19:21

US3742148

Folder: SAE USA-US127-2021-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 10 Jun 2021 09:27:01

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 15:27:15
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 17:03:33
Un-reviewed for Safety.	System	25 Feb 2021 14:10:32
DataPoint Un-verified.	System	25 Feb 2021 14:10:32
Signature has been broken.	System	25 Feb 2021 14:10:32
User entered 'Yes (Y)'	System	25 Feb 2021 14:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered 'No (N)'	System	04 Feb 2021 17:19:21

**US3742148**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:27:01**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered 'Karen'	System	04 Feb 2021 17:19:21

**US3742148**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:27:01**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered 'Kotloff'	System	04 Feb 2021 17:19:21



**US3742148**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:27:01**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered '685 W. Baltimore Street, HSF 480'	System	04 Feb 2021 17:19:21

**US3742148**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:27:01**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered 'Baltimore'	System	04 Feb 2021 17:19:21

**US3742148**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:27:01**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:19:46
User entered '21201'	System	04 Feb 2021 17:19:21

**US3742148**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:27:01**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 17:03:33
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 19:14:18
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
User entered 'US'	(b) (4) System	04 Feb 2021 17:19:53

**US3742148**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:27:01**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	26 Feb 2021 17:03:50
User entered '2'	System	26 Feb 2021 17:03:50
User signature succeeded.	Karen Kotloff (b) (4)	23 Feb 2021 17:23:38
	(b) (4)	
User entered '1'	System	04 Feb 2021 17:19:53

**US3742148**

**Folder: SAE USA-US127-2021-MRNA-1273-P301000010**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:27:01**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 15:27:15
User entered '26/Feb/2021 12:03'	System	26 Feb 2021 17:03:50

US3742148

Folder: SAE USA-US127-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:27:01

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Milagritos Tapia (b) (4)	07 Apr 2021 21:08:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 15:27:15
User entered 'I'	(b) (4), (b) (6)	26 Feb 2021 17:03:50