

US3432242 (Prod: Brigham and Womens Hospital)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:37:31

All time stamps listed in this document are displayed in GMT

US3432242

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 02:08:51

Generated On: 09 Jun 2021 17:37:31

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Participant ID

US3432242

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

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US3432242

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 02:08:52

Generated On: 09 Jun 2021 17:37:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 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) 19 Feb 2021 02:08:52

Generated On: 09 Jun 2021 17:37:31

Date of Birth (MMM yyyy)	(b) (6) 1950
Age	70
Age Units	YEARS
Age (Derived)	70
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 02:08:52

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	22 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 02:08:52

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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) 19 Feb 2021 02:08:52

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 02:08:52

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Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 02:08:52

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Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Start Year (derived)	2001
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 02:08:52

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Condition	INSOMNIA
Start date (dd MMM yyyy)	UN JUL 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 02:08:52

Generated On: 09 Jun 2021 17:37:31

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 02:08:52

Generated On: 09 Jun 2021 17:37:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	22 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	08:45 (24 HR)
Vital Signs Date and Time (derived)	22 AUG 2020 08:45
Height ( <i>xxx.x</i> )	181 cm
Weight ( <i>xxx.x</i> )	71.6 kg
BMI ( <i>xxx.x</i> )	21.85525 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) 19 Feb 2021 02:08:52

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 02:08:52

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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** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 02:08:52

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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)	True
<b>Other</b>	False
<b>Specify</b>	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 02:08:52

Generated On: 09 Jun 2021 17:37:31

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

Visit date (dd MMM yyyy)	22 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 02:08:52

Generated On: 09 Jun 2021 17:37:31

What was the date of randomization? (dd MMM yyyy) 22 AUG 2020

What was the participant's randomization number? 187775

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) 19 Feb 2021 02:08:52

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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) 19 Feb 2021 02:08:52

Generated On: 09 Jun 2021 17:37:31

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 AUG 2020
Time of assessment (00:00-23:59)	8:45 (24 HR)
Vital Signs Date and Time (derived)	22 AUG 2020 8:45
Temperature (xxx.x)	37 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 02:08:52

Generated On: 09 Jun 2021 17:37:31

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 AUG 2020
Time of assessment (00:00-23:59)	10:07 (24 HR)
Vital Signs Date and Time (derived)	22 AUG 2020 10:07
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	156 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 02:08:52

Generated On: 09 Jun 2021 17:37:31

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 02:08:52

Generated On: 09 Jun 2021 17:37:31

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 22 AUG 2020

What was the treatment time? (00:00-23:59) 9:32 (24 HR)

Treatment Date and Time (derived) 22 AUG 2020 9:32

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) 19 Feb 2021 02:08:52

Generated On: 09 Jun 2021 17:37:31

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

Collection date (dd MMM yyyy)	22 AUG 2020
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Collection time (00:00-23:59)	9:10 (24 HR)
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Collection date and time (derived)	22 AUG 2020 9:10
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US3432242

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 02:08:52

Generated On: 09 Jun 2021 17:37:31

Collection date (dd MMM yyyy)			22 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:16	22 AUG 2020 09:16
Nasopharyngeal Swab 2	No		



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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:08:52

Generated On: 09 Jun 2021 17:37:31

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: 09 Jun 2021 17:37:31

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐  
No ☒

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

PC Time Stamp 22 AUG 2020 10:17

PC Open Date & Time 22 AUG 2020 09:52

PC Close Date & Time 22 AUG 2020 12:22

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

97.4 °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	23 AUG 2020 10:05
PC Open Date & Time	22 AUG 2020 13:17
PC Close Date & Time	23 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:37:31

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**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

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Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.5 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

24 AUG 2020 07:33

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PC Open Date & Time

23 AUG 2020 12:00

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PC Close Date & Time

24 AUG 2020 11:59

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US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 08:18

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 08:07

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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 AUG 2020 08:23

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:37:31

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 07:37

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59



US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 10:06

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 10:18

PC Open Date & Time

22 AUG 2020 09:52

PC Close Date & Time

22 AUG 2020 12:22

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

1

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

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

23 AUG 2020 10:07

PC Open Date & Time

22 AUG 2020 13:17

PC Close Date & Time

23 AUG 2020 11:59

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

1

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

24 AUG 2020 07:34

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 08:18

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 08:07

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 08:24

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 07:38

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59



US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 10:07

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

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

No ☒

Yes ☐

PC Time stamp	22 AUG 2020 10:19
PC Open Date & Time	22 AUG 2020 09:52
PC Close Date & Time	22 AUG 2020 12:22

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

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

No ☒

Yes ☐

PC Time stamp	23 AUG 2020 10:08
PC Open Date & Time	22 AUG 2020 13:17
PC Close Date & Time	23 AUG 2020 11:59

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:37:31

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 07:35
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:37:31

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 08:19
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:37:31

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 08:08
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:37:31

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 08:24
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:37:31

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 07:38
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:37:31

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 10:07
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3432242

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3432242

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**  
**ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time stamp

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3432242

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:37:31

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3432242

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 17:37:31

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3432242

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:08:51

Generated On: 09 Jun 2021 17:37:31

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3432242

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:08:51

Generated On: 09 Jun 2021 17:37:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432242

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:08:51

Generated On: 09 Jun 2021 17:37:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3432242

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:08:51

Generated On: 09 Jun 2021 17:37:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432242

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:08:51

Generated On: 09 Jun 2021 17:37:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3432242

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:08:51

Generated On: 09 Jun 2021 17:37:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432242

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 02:08:52

Generated On: 09 Jun 2021 17:37:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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

US3432242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 02:08:52

Generated On: 09 Jun 2021 17:37:31

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 SEP 2020
Time of assessment (00:00-23:59)	8:17 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 8:17
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	156 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3432242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 02:08:52

Generated On: 09 Jun 2021 17:37:31

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	21 SEP 2020
Time of assessment (00:00-23:59)	9:30 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 9:30
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	166 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3432242

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 02:08:52

Generated On: 09 Jun 2021 17:37:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

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

US3432242

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 02:08:52

Generated On: 09 Jun 2021 17:37:31

Was study treatment given? Yes ☒  
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 21 SEP 2020

What was the treatment time? (00:00-23:59) 08:58 (24 HR)

Treatment Date and Time (derived) 21 SEP 2020 08:58

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

What was the frequency of the study treatment dosing? ONCE

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



US3432242

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 02:08:52

Generated On: 09 Jun 2021 17:37:31

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 SEP 2020

Collection time (00:00-23:59)

08:35 (24 HR)

Collection date and time (derived)

21 SEP 2020 08:35

US3432242

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 02:08:52

Generated On: 09 Jun 2021 17:37:31

Collection date (dd MMM yyyy)			21 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:43	21 SEP 2020 08:43
Nasopharyngeal Swab 2	No		

US3432242

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:08:52

Generated On: 09 Jun 2021 17:37:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 09:35

PC Open Date & Time

21 SEP 2020 09:18

PC Close Date & Time

21 SEP 2020 11:48

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 101.7 °F

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

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

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

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

PC Time Stamp 22 SEP 2020 07:33

PC Open Date & Time 21 SEP 2020 12:43

PC Close Date & Time 22 SEP 2020 11:59

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

23 SEP 2020 09:09

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

24 SEP 2020 18:38

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59



US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

26 SEP 2020 10:04

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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 11:06

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 7

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

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

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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

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 09:35

PC Open Date & Time

21 SEP 2020 09:18

PC Close Date & Time

21 SEP 2020 11:48

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

5

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 07:36

PC Open Date & Time

21 SEP 2020 12:43

PC Close Date & Time

22 SEP 2020 11:59

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 09:10

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 18:38

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59



US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

26 SEP 2020 10:04

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 11:07

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 7

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

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

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 09:36
PC Open Date & Time	21 SEP 2020 09:18
PC Close Date & Time	21 SEP 2020 11:48

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

**HEADACHE**

- None ☐
- No interference with activity ☐
- Repeated use of over-the-counter  
pain reliever > 24 hours or some  
interference with activity ☒
- Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily  
activity ☒

**MUSCLE ACHES ALL OVER BODY**

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily  
activity ☒

**JOINT ACHES IN SEVERAL JOINTS**

- None ☐
- No interference with activity ☐
- Some interference with activity ☐
- Significant; prevents daily  
activity ☒

**NAUSEA/VOMITING**

- None ☐
- No interference with activity or  
1-2 episodes/24 hours ☐
- Some interference with activity  
or >2 episodes/24 hours ☒
- Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

- None ☐
- No interference with activity ☐
- Some interference with activity  
not requiring medical attention ☒
- Prevents daily activity and  
requires medical attention ☐

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

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

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 07:37
PC Open Date & Time	21 SEP 2020 12:43
PC Close Date & Time	22 SEP 2020 11:59

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒



US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:37:31

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 09:11
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:37:31

Yes ☐

PC Time stamp

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:37:31

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 18:39
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:37:31

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 10:05
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)



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Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:37:31

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

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

**DAY 7**

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:37:31

Yes ☐

PC Time stamp

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3432242

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:08:51

Generated On: 09 Jun 2021 17:37:31

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3432242

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:08:51

Generated On: 09 Jun 2021 17:37:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432242

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:08:51

Generated On: 09 Jun 2021 17:37:31

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3432242

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:08:51

Generated On: 09 Jun 2021 17:37:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432242

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:08:51

Generated On: 09 Jun 2021 17:37:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3432242

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:08:51

Generated On: 09 Jun 2021 17:37:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432242

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 02:08:52

Generated On: 09 Jun 2021 17:37:31

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

US3432242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 02:08:52

Generated On: 09 Jun 2021 17:37:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 OCT 2020
Time of assessment (00:00-23:59)	08:06 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 08:06
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	INFRA-RED
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	065 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432242

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 02:08:52

Generated On: 09 Jun 2021 17:37:31

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3432242

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 02:08:52

Generated On: 09 Jun 2021 17:37:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 OCT 2020
Collection time (00:00-23:59)	08:33 (24 HR)
Collection date and time (derived)	23 OCT 2020 08:33

US3432242

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:08:52

Generated On: 09 Jun 2021 17:37:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	22 OCT 2020 11:34:36
Patient Cloud Open Date & Time	22 OCT 2020 00:01
Patient Cloud Close Date & Time	26 OCT 2020 23:59

US3432242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	29 OCT 2020 23:00:51
Patient Cloud Open Date & Time	29 OCT 2020 00:01
Patient Cloud Close Date & Time	02 NOV 2020 23:59



US3432242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 NOV 2020 11:34:48
Patient Cloud Open Date & Time	05 NOV 2020 00:01
Patient Cloud Close Date & Time	09 NOV 2020 23:59

US3432242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="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"/>

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	19 NOV 2020 22:03:04
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 NOV 2020 18:06:45
Patient Cloud Open Date & Time	23 NOV 2020 00:01
Patient Cloud Close Date & Time	27 NOV 2020 23:59

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 NOV 2020 11:31:54

Patient Cloud Open Date & Time

30 NOV 2020 00:01

Patient Cloud Close Date & Time

04 DEC 2020 23:59

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	07 DEC 2020 07:28:33
Patient Cloud Open Date & Time	07 DEC 2020 00:01
Patient Cloud Close Date & Time	11 DEC 2020 23:59

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 DEC 2020 14:44:06

Patient Cloud Open Date & Time

14 DEC 2020 00:01

Patient Cloud Close Date & Time

18 DEC 2020 23:59



US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	21 DEC 2020 13:39:49
Patient Cloud Open Date & Time	21 DEC 2020 00:01
Patient Cloud Close Date & Time	25 DEC 2020 23:59

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 DEC 2020 15:31:12

Patient Cloud Open Date & Time

28 DEC 2020 00:01

Patient Cloud Close Date & Time

01 JAN 2021 23:59

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 JAN 2021 07:36:00

Patient Cloud Open Date & Time

04 JAN 2021 00:01

Patient Cloud Close Date & Time

08 JAN 2021 23:59

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

<b>TIMEPOINT</b>	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 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	11 JAN 2021 07:09:02
Patient Cloud Open Date & Time	11 JAN 2021 00:01
Patient Cloud Close Date & Time	15 JAN 2021 23:59

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 JAN 2021 11:39:46

Patient Cloud Open Date & Time

18 JAN 2021 00:01

Patient Cloud Close Date & Time

22 JAN 2021 23:59

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 JAN 2021 11:38:32

Patient Cloud Open Date & Time

25 JAN 2021 00:01

Patient Cloud Close Date & Time

29 JAN 2021 23:59

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 FEB 2021 16:42:01
Patient Cloud Open Date & Time	01 FEB 2021 00:01
Patient Cloud Close Date & Time	05 FEB 2021 23:59

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 FEB 2021 17:46:21

Patient Cloud Open Date & Time

08 FEB 2021 00:01

Patient Cloud Close Date & Time

12 FEB 2021 23:59



US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 FEB 2021 06:59:45

Patient Cloud Open Date & Time

15 FEB 2021 00:01

Patient Cloud Close Date & Time

19 FEB 2021 23:59

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	22 FEB 2021 08:36:30
Patient Cloud Open Date & Time	22 FEB 2021 00:01
Patient Cloud Close Date & Time	26 FEB 2021 23:59

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 MAR 2021 13:31:25
Patient Cloud Open Date & Time	01 MAR 2021 00:01
Patient Cloud Close Date & Time	05 MAR 2021 23:59

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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[Patient Cloud Open Date & Time](#)

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08 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 MAR 2021 23:59

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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 MAR 2021 15:38:46

Patient Cloud Open Date & Time

15 MAR 2021 00:01

Patient Cloud Close Date & Time

19 MAR 2021 23:59

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 MAR 2021 20:49:07

Patient Cloud Open Date & Time

22 MAR 2021 00:01

Patient Cloud Close Date & Time

26 MAR 2021 23:59

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 MAR 2021 08:54:18

Patient Cloud Open Date & Time

29 MAR 2021 00:01

Patient Cloud Close Date & Time

02 APR 2021 23:59



US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 APR 2021 18:15:26

Patient Cloud Open Date & Time

05 APR 2021 00:01

Patient Cloud Close Date & Time

09 APR 2021 23:59

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

<b>TIMEPOINT</b>	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	12 APR 2021 06:58:03
Patient Cloud Open Date & Time	12 APR 2021 00:01
Patient Cloud Close Date & Time	16 APR 2021 23:59

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 APR 2021 15:30:26

Patient Cloud Open Date & Time

19 APR 2021 00:01

Patient Cloud Close Date & Time

23 APR 2021 23:59

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 12:40:00

Patient Cloud Open Date & Time

26 APR 2021 00:01

Patient Cloud Close Date & Time

30 APR 2021 23:59

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAY 2021 07:03:35

Patient Cloud Open Date & Time

03 MAY 2021 00:01

Patient Cloud Close Date & Time

07 MAY 2021 23:59

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

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

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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[Patient Cloud Open Date & Time](#)

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10 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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14 MAY 2021 23:59

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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>



**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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[Patient Cloud Open Date & Time](#)

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17 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 MAY 2021 23:59

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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 MAY 2021 23:59

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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[Patient Cloud Open Date & Time](#)

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31 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 JUN 2021 23:59

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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

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

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	07 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 JUN 2021 23:59

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>



**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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[Patient Cloud Open Date & Time](#)

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14 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 JUN 2021 23:59

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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 JUN 2021 23:59

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	28 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 JUL 2021 23:59

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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[Patient Cloud Open Date & Time](#)

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05 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 JUL 2021 23:59

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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

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



**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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[Patient Cloud Open Date & Time](#)

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02 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 AUG 2021 23:59

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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

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

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



**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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[Patient Cloud Open Date & Time](#)

09 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 362

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

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

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

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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[Patient Cloud Open Date & Time](#)

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23 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 AUG 2021 23:59

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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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[Patient Cloud Open Date & Time](#)

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30 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 SEP 2021 23:59

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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 397

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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[Patient Cloud Open Date & Time](#)

20 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

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

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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[Patient Cloud Open Date & Time](#)

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27 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 OCT 2021 23:59

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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	04 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	08 OCT 2021 23:59

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 418

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 432

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

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

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 OCT 2021 23:59
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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

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



**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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[Patient Cloud Open Date & Time](#)

01 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 NOV 2021 23:59

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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

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

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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[Patient Cloud Open Date & Time](#)

08 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59

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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

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



**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 DEC 2021 23:59

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

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

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

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	20 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 DEC 2021 23:59
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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 DEC 2021 23:59

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 JAN 2022 23:59

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

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

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

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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[Patient Cloud Open Date & Time](#)

10 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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[Patient Cloud Open Date & Time](#)

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17 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 JAN 2022 23:59

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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

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

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



**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	31 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 FEB 2022 23:59

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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[Patient Cloud Open Date & Time](#)

07 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 544

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

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

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



**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

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

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

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

[Patient Cloud Open Date & Time](#)

28 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

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

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

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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[Patient Cloud Open Date & Time](#)

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07 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAR 2022 23:59

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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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[Patient Cloud Open Date & Time](#)

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14 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAR 2022 23:59

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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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[Patient Cloud Open Date & Time](#)

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21 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAR 2022 23:59

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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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[Patient Cloud Open Date & Time](#)

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28 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 APR 2022 23:59

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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 593

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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[Patient Cloud Open Date & Time](#)

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04 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 APR 2022 23:59

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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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[Patient Cloud Open Date & Time](#)

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11 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 APR 2022 23:59

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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 APR 2022 23:59

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

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

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

[Patient Cloud Open Date & Time](#)

25 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 APR 2022 23:59

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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[Patient Cloud Open Date & Time](#)

02 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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[Patient Cloud Open Date & Time](#)

09 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 MAY 2022 23:59

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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>



**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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[Patient Cloud Open Date & Time](#)

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16 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAY 2022 23:59

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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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[Patient Cloud Open Date & Time](#)

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23 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAY 2022 23:59

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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 649

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

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

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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[Patient Cloud Open Date & Time](#)

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30 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 JUN 2022 23:59

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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

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

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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[Patient Cloud Open Date & Time](#)

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06 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 JUN 2022 23:59

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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

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

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



**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 JUN 2022 23:59

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

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

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 JUN 2022 23:59

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

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

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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[Patient Cloud Open Date & Time](#)

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04 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 JUL 2022 23:59

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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

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



**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

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

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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[Patient Cloud Open Date & Time](#)

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18 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 JUL 2022 23:59

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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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[Patient Cloud Open Date & Time](#)

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25 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 JUL 2022 23:59

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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 AUG 2022 23:59

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

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



**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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[Patient Cloud Open Date & Time](#)

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08 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 AUG 2022 23:59

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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	15 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 AUG 2022 23:59
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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 733

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

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

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

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

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

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

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 ☐

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

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

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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[Patient Cloud Open Date & Time](#)

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29 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 SEP 2022 23:59

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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

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



**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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[Patient Cloud Open Date & Time](#)

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05 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 SEP 2022 23:59

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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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[Patient Cloud Open Date & Time](#)

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19 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 SEP 2022 23:59

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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

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[Patient Cloud Open Date & Time](#)

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26 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 SEP 2022 23:59

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US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 OCT 2022 23:59

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 782

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

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

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

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3432242**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 OCT 2022 23:59

US3432242

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:37:31

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		02 MAR 2021 13:31:38



US3432242

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:08:52

Generated On: 09 Jun 2021 17:37:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3432242

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:08:52

Generated On: 09 Jun 2021 17:37:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432242

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:08:51

Generated On: 09 Jun 2021 17:37:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3432242

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:08:51

Generated On: 09 Jun 2021 17:37:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432242

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:08:51

Generated On: 09 Jun 2021 17:37:31

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 JAN 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3432242

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:08:51

Generated On: 09 Jun 2021 17:37:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432242

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 20:43:02

Generated On: 09 Jun 2021 17:37:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3432242

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 20:43:02

Generated On: 09 Jun 2021 17:37:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3432242

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 04 Apr 2021 20:43:14

Generated On: 09 Jun 2021 17:37:31

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

Visit date (dd MMM yyyy)	19 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3432242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 04 Apr 2021 20:43:14

Generated On: 09 Jun 2021 17:37:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 MAR 2021
Time of assessment (00:00-23:59)	08:06 (24 HR)
Vital Signs Date and Time (derived)	19 MAR 2021 08:06
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	162 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432242

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 04 Apr 2021 20:43:02

Generated On: 09 Jun 2021 17:37:31

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3432242

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 04 Apr 2021 20:43:02

Generated On: 09 Jun 2021 17:37:31

Was the sample collected? Yes ☒  
No ☐

Collection date (dd MMM yyyy) 19 MAR 2021

Collection time (00:00-23:59) 08:20 (24 HR)

Collection date and time (derived) 19 MAR 2021 08:20

US3432242

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 20:43:02

Generated On: 09 Jun 2021 17:37:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3432242**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:37:31**

Was Contact Attempted? Yes ☐  
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

**US3432242**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:37:31**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3432242

Folder: Covid-19 Assessment 31 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 19 Feb 2021 02:08:51

Generated On: 09 Jun 2021 17:37:31

Date of Contact									
Time of Contact									
Date and Time of Contact (derived)									
Type of Contact	<table><tr><td>Clinic Visit - Scheduled</td><td><input type="checkbox"/></td></tr><tr><td>Clinical Visit - Unscheduled</td><td><input type="checkbox"/></td></tr><tr><td>Safety Call</td><td><input type="checkbox"/></td></tr><tr><td>Convalescent Tele-visit</td><td><input type="checkbox"/></td></tr></table>	Clinic Visit - Scheduled	<input type="checkbox"/>	Clinical Visit - Unscheduled	<input type="checkbox"/>	Safety Call	<input type="checkbox"/>	Convalescent Tele-visit	<input type="checkbox"/>
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?	<table><tr><td>Yes</td><td><input type="checkbox"/></td></tr><tr><td>No</td><td><input type="checkbox"/></td></tr></table>	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>				
Yes	<input type="checkbox"/>								
No	<input type="checkbox"/>								



**US3432242**

**Folder: Covid-19 Assessment 31 Oct 2020**

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

**Generated On: 09 Jun 2021 17:37:31**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3432242

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 02:08:51

Generated On: 09 Jun 2021 17:37:31

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

Visit date (dd MMM yyyy)	08 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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US3432242

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

Form: Unblinding

Data signed: (b) (4) 25 Apr 2021 11:09:13

Generated On: 09 Jun 2021 17:37:31

Date of updated informed consent (dd MMM yyyy) 6 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) 08 JAN 2021

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 \_\_\_\_\_

US3432242

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 02:08:51

Generated On: 09 Jun 2021 17:37:31

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

Collection date (dd MMM yyyy)	08 JAN 2021
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Collection time (00:00-23:59)	08:16 (24 HR)
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Collection date and time (derived)	08 JAN 2021 08:16
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US3432242

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 02:08:51

Generated On: 09 Jun 2021 17:37:31

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

Collection date (dd MMM yyyy)	08 JAN 2021
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Collection time (00:00 - 23:59)	08:21
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Collection Date and Time (derived)	08 JAN 2021 08:21
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US3432242

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 02:08:51

Generated On: 09 Jun 2021 17:37:31

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

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US3432242

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Feb 2021 02:08:51

Generated On: 09 Jun 2021 17:37:31

AEID	USA-US078-2020-MRNA-1273-P30 1000006
Adverse event	MARGINAL ZONE SPLENIC B-CELL LYMPHOMA
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)	8 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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) 19 Feb 2021 02:08:51

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



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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Feb 2021 02:08:51

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ROUTINE CBC DONE ON SEPT  
28TH IN PREPARATION FOR  
REGULAR PCP APPOINTMENT  
SHOWED LYMPHOCYTOSIS.  
BLOOD COUNT REPEATED ON  
08OCT2020 WITH FLOW  
CYTOMETRY CONFIRMING  
CLL. HAS A PLANNED  
APPOINTMENT ON 11/11 WITH  
HEMATOLOGIST. ADDITIONAL  
FLOW CYTOMETRY RAN  
06NOV2020.  
30OCT2020: WBC: 28SEP2020 17.6  
X 10<sup>3</sup> / UL; 08OCT2020 21.3 X  
10<sup>3</sup> / UL

08OCT2020: FLOW CYTOMETRY  
RESULTS:  
IMMUNOPHENOTYPIC  
FINDINGS IN KEEPING WITH  
INVOLVEMENT BY A CD5  
NEGATIVE/CD10 NEGATIVE  
B-CELL NON-HODGKIN  
LYMPHOMA. THIS  
IMMUNOPHENOTYPE IS  
NON-SPECIFIC.  
APPROXIMATELY 86% OF  
TOTAL ACQUIRED EVENTS ARE  
EVALUABLE NON-DEBRIS  
EVENTS.

THE VIABILITY OF THE  
ANALYZED NON-DEBRIS  
EVENTS DONE BY 7-AAD IS  
95%. CD45-BRIGHT,

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Folder: Adverse Events

Form: Adverse Events (1)

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LOW SIDE-SCATTER GATED  
LYMPHOCYTES COMPRISE 81%  
OF TOTAL ANALYZED EVENTS.  
B CELLS COMPRISE 76% OF  
LYMPHOID-GATED EVENTS  
AND DEMONSTRATE  
MONOCLONAL KAPPA LIGHT  
CHAIN RESTRICTION (BRIGHT  
KAPPA EXPRESSION SEEN).  
THEY CO-EXPRESS PAN-B CELL  
MARKERS CD19, CD20 AND  
CD22 ALONG WITH CD11C  
(SUBSET DIM). THEY DO NOT  
EXPRESS ANY OTHER  
CHARACTERISTIC ANTIGENS  
INCLUDING CD5, CD10, CD23,  
CD25, CD34, CD38 AND CD103. T  
CELLS COMPRISE 24% OF  
LYMPHOID GATED EVENTS  
AND EXPRESS MATURE  
LINEAGE ANTIGENS (CD3, CD5,  
CD2 AND CD7). A SUBSET OF T  
CELLS SHOWS DIM/VARIABLE  
LOSS OF CD7 (FAVOR  
NON-SPECIFIC FINDING). T  
CELLS HAVE A CD4:CD8 RATIO  
OF 0.9. CD56 POSITIVE, CD3  
NEGATIVE NATURAL KILLER  
CELLS REPRESENT 3% OF  
GATED LYMPHOCYTES.

06NOV2020: FLOW CYTOMETRY  
RESULTS:  
ABERRANT POPULATION OF

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Folder: Adverse Events

Form: Adverse Events (1)

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B CELLS (72% OF GATED  
EVENTS; 53% OF TOTAL  
EVENTS) POSITIVE FOR  
B-LYMPHOID MARKERS CD19,  
CD20, CO-EXPRESSES CD11C,  
EXHIBITS  
BRIGHT MONOTYPIC STAINING  
FOR SURFACE  
IMMUNOGLOBULIN KAPPA,  
AND NEGATIVE FOR CD10, CD5,  
CD23, CD38, CD25, CD103, AND  
OTHER T-CELL MARKERS,  
CONSISTENT WITH  
INVOLVEMENT BY A B-CELL  
LYMPHOPROLIFERATIVE  
DISORDER.

BASED ON RESULTS,  
DIAGNOSIS WAS UPDATED. PT  
IS ASYMPTOMATIC  
CURRENTLY. NO TREATMENT  
STARTED.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 04 Apr 2021 20:43:02

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

Yes ☒

No ☐

---

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

---

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 25 Apr 2021 11:09:13

Generated On: 09 Jun 2021 17:37:31

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 25 Apr 2021 11:09:13

Generated On: 09 Jun 2021 17:37:31

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 25 Apr 2021 11:09:13

Generated On: 09 Jun 2021 17:37:31

Name of Medication FLUOXETINE

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 25 Apr 2021 11:09:13

Generated On: 09 Jun 2021 17:37:31

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2001	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 25 Apr 2021 11:09:13

Generated On: 09 Jun 2021 17:37:31

Name of Medication MELATONINE

Prophylaxis Yes ☐  
No ☒

Indication INSOMNIA

Dose per administration 3

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) 25 Apr 2021 11:09:13

Generated On: 09 Jun 2021 17:37:31

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 25 Apr 2021 11:09:13

Generated On: 09 Jun 2021 17:37:31

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication FEVER, HEADACHE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 25 Apr 2021 11:09:13

Generated On: 09 Jun 2021 17:37:31

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 25 Apr 2021 11:09:13

Generated On: 09 Jun 2021 17:37:31

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify VACCINATION

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 25 Apr 2021 11:09:13

Generated On: 09 Jun 2021 17:37:31

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 25 Apr 2021 11:09:13

Generated On: 09 Jun 2021 17:37:31

Name of Medication SHINGRIX VACCINATION

Prophylaxis Yes ☒  
No ☐

Indication PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 25 Apr 2021 11:09:13

Generated On: 09 Jun 2021 17:37:31

	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)		8 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)		8 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 Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 04 Apr 2021 20:43:02

Generated On: 09 Jun 2021 17:37:31

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Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 25 Apr 2021 11:09:13

Generated On: 09 Jun 2021 17:37:31

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
28 SEP 2020	ROUTINE CBC	Other	GENERAL HEALTH
08 OCT 2020	BLOOD COUNT REPEAT	Diagnostic	
06 NOV 2020	FLOW CYTOMETRY	Diagnostic	
31 DEC 2020	CT SCAN (NECK TO PELVIS)	Diagnostic	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:37:31

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:37:31

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by  
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 19 Feb 2021 02:08:51

Generated On: 09 Jun 2021 17:37:31

SAEID	USA-US078-2020-MRNA-1273-P301000006
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	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 19 Feb 2021 02:08:51

Generated On: 09 Jun 2021 17:37:31

SAEID	USA-US078-2020-MRNA-1273-P301000006
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	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	19/OCT/2020 12:21
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

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 19 Feb 2021 02:08:51

Generated On: 09 Jun 2021 17:37:31

SAEID	USA-US078-2020-MRNA-1273-P301000006
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	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	02/NOV/2020 13:56
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

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 19 Feb 2021 02:08:51

Generated On: 09 Jun 2021 17:37:31

SAEID	USA-US078-2020-MRNA-1273-P301000006
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	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	11/FEB/2021 10:11
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

US3432242 (Prod: Brigham and Womens Hospital)

**US3432242**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:37:31**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'US3432242'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 12:44:16

US3432242

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:37:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	22 Aug 2020 13:29:05

US3432242

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:37:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '22 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 12:44:17

US3432242

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:37:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Clinic (Clinic)'	Phoebe Cunningham (b) (4)	22 Aug 2020 13:29:05

**US3432242**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:37:31**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User entered 'SCRN'	System	22 Aug 2020 13:29:05

US3432242

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:37:31

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered (b) (6) 1950'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 12:44:18

**US3432242**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:37:31**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '70'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:04:37



**US3432242**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:37:31**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User entered 'YEARS'	System	22 Aug 2020 16:04:37

**US3432242**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:37:31**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User entered '70'	System	22 Aug 2020 13:29:22

US3432242

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:37:31

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Male (M)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:04:37

US3432242

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:37:31

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:04:37

US3432242

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:37:31

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'I'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:04:37

US3432242

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:37:31

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '0'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:04:37

**US3432242**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:37:31**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '0'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:04:37

US3432242

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:37:31

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '0'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:04:37



US3432242

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:37:31

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '0'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:04:37

**US3432242**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:37:31**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '0'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:04:37

US3432242

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:37:31

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	Phoebe Cunningham (b) (4)	22 Aug 2020 16:04:37

**US3432242**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:37:31**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '0'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:04:37

US3432242

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:37:31

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '0'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:04:37

US3432242

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:37:31

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '22 Aug 2020'	Phoebe Cunningham (b) (4)	22 Aug 2020 13:29:22

**US3432242**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:37:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User entered 'Aug 2020'	System	22 Aug 2020 13:29:22

US3432242

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:37:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User entered '2020'	System	22 Aug 2020 13:29:22



**US3432242**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:37:31**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Amendment 2 (2)'	Phoebe Cunningham (b) (4)	22 Aug 2020 13:29:22

US3432242

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:37:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	22 Aug 2020 13:29:22

US3432242

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:37:31

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	Phoebe Cunningham (b) (4)	22 Aug 2020 13:29:22

US3432242

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:37:31

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	Phoebe Cunningham (b) (4)	22 Aug 2020 13:29:22

US3432242

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:37:31

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'No (N)'	Phoebe Cunningham (b) (4)	22 Aug 2020 13:29:22

US3432242

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:37:31

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 12:44:17

US3432242

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:37:31

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User entered 'I'	System	22 Aug 2020 13:29:28

US3432242

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:37:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	22 Aug 2020 13:29:28



US3432242

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:37:31

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:00:15

US3432242

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:37:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 16:02:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 16:02:12
Data point term sent to Coder	System	22 Aug 2020 16:01:53
User entered 'Hypercholesterolemia'	Phoebe Cunningham	22 Aug 2020 16:01:20
	(b) (4)	

US3432242

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:37:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'un UNK 2014'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:01:20

US3432242

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:37:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '0'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:01:20

**US3432242**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:37:31**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:01:20

US3432242

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:37:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	Phoebe Cunningham (b) (4)	22 Aug 2020 16:01:20

US3432242

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:37:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '0'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:01:20

US3432242

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:37:31

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User entered 'Jan 2014'	System	22 Aug 2020 16:01:20



US3432242

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:37:31

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User entered '2014'	System	22 Aug 2020 16:01:20

**US3432242**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:37:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User entered empty.	System	22 Aug 2020 16:01:20

**US3432242**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:37:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User entered empty.	System	22 Aug 2020 16:01:20

US3432242

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:37:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 16:02:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 16:02:11
Data point term sent to Coder	System	22 Aug 2020 16:01:52
User entered 'Anxiety'	Phoebe Cunningham	22 Aug 2020 16:01:38
	(b) (4)	

**US3432242**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:37:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'un UNK 2001'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:01:38

US3432242

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:37:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '0'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:01:38

**US3432242**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:37:31**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:01:38

US3432242

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:37:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	Phoebe Cunningham (b) (4)	22 Aug 2020 16:01:38



US3432242

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:37:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '0'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:01:38

US3432242

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:37:31

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User entered 'Jan 2001'	System	22 Aug 2020 16:01:38

**US3432242**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:37:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User entered '2001'	System	22 Aug 2020 16:01:38

US3432242

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:37:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User entered empty.	System	22 Aug 2020 16:01:38

US3432242

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:37:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User entered empty.	System	22 Aug 2020 16:01:38

US3432242

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:37:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 16:04:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Aug 2020 16:04:13
Data point term sent to Coder	System	22 Aug 2020 16:02:53
User entered 'Insomnia'	Phoebe Cunningham	22 Aug 2020 16:01:59
	(b) (4)	

US3432242

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:37:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'un Jul 2020'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:01:59

US3432242

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:37:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '0'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:01:59



US3432242

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:37:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:01:59

US3432242

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:37:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	Phoebe Cunningham (b) (4)	22 Aug 2020 16:01:59

US3432242

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:37:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '0'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:01:59

**US3432242**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:37:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User entered 'Jul 2020'	System	22 Aug 2020 16:01:59

US3432242

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:37:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User entered '2020'	System	22 Aug 2020 16:01:59

**US3432242**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:37:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User entered empty.	System	22 Aug 2020 16:01:59

**US3432242**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:37:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User entered empty.	System	22 Aug 2020 16:01:59

US3432242

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:37:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
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 for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 07:59:49
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' answered with 'per ppt, no medication is taken. condition is ppt reported' (Site from DM).	Julia Klopfer (b) (4)	23 Oct 2020 12:20:11
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 for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 17:23:57
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 14:33:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 14:33:45
Data point term sent to Coder	System	21 Sep 2020 14:33:18
User entered 'Hypertension'	(b) (4), (b) (6)	21 Sep 2020 14:32:45



**US3432242**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:37:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'un UNK 2019'	(b) (4), (b) (6)	21 Sep 2020 14:32:45

US3432242

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:37:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '0'	(b) (4), (b) (6)	21 Sep 2020 14:32:45

**US3432242**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:37:31**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 14:32:45

**US3432242**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:37:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 14:32:45

**US3432242**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:37:31**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '0'	(b) (4), (b) (6)	21 Sep 2020 14:32:45

**US3432242**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:37:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User entered 'Jan 2019'	System	21 Sep 2020 14:32:45

**US3432242**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:37:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User entered '2019'	System	21 Sep 2020 14:32:45

**US3432242**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:37:31**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User entered empty.	System	21 Sep 2020 14:32:45



US3432242

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:37:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User entered empty.	System	21 Sep 2020 14:32:45

US3432242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:02:44

US3432242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '22 Aug 2020'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:02:44

**US3432242**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:37:31**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '08:45'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:02:44

US3432242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User entered '22 Aug 2020 08:45'	System	22 Aug 2020 16:02:44

US3432242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '181' cm	Phoebe Cunningham (b) (4)	22 Aug 2020 16:02:44
DataPoint set to visible.	System	22 Aug 2020 13:29:28

US3432242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '71.6' kg	Phoebe Cunningham (b) (4)	22 Aug 2020 16:02:44
DataPoint set to visible.	System	22 Aug 2020 13:29:28

US3432242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
Amendment Manager: User entered '21.85525'	System	17 Sep 2020 00:19:45
User entered '21.9'	System	22 Aug 2020 16:02:44
DataPoint set to visible.	System	22 Aug 2020 13:29:28



US3432242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User entered 'kg/m2'	System	22 Aug 2020 16:02:44
DataPoint set to visible.	System	22 Aug 2020 13:29:28

US3432242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Aug 2020 16:03:34
User entered missing code ND - Not Done; reason for change Data Entry Error	Phoebe Cunningham (b) (4)	22 Aug 2020 16:03:34
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Aug 2020 16:02:44
User entered 'N' (non-conformant).	Phoebe Cunningham (b) (4)	22 Aug 2020 16:02:44

US3432242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	Phoebe Cunningham (b) (4)	22 Aug 2020 16:02:44

US3432242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	Phoebe Cunningham (b) (4)	22 Aug 2020 16:02:44

US3432242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Aug 2020 16:03:34
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	22 Aug 2020 16:03:34
User entered missing code ND - Not Done; reason for change Data Entry Error	Phoebe Cunningham (b) (4)	22 Aug 2020 16:03:34
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Aug 2020 16:02:44
User entered empty.	Phoebe Cunningham (b) (4)	22 Aug 2020 16:02:44

**US3432242**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:37:31**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User entered 'bpm'	System	22 Aug 2020 16:03:34
User entered empty.	System	22 Aug 2020 16:02:44

US3432242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Aug 2020 16:03:34
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	22 Aug 2020 16:03:34
User entered missing code ND - Not Done; reason for change Data Entry Error	Phoebe Cunningham (b) (4)	22 Aug 2020 16:03:34
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Aug 2020 16:02:44
User entered empty.	Phoebe Cunningham (b) (4)	22 Aug 2020 16:02:44

US3432242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User entered 'breaths/min'	System	22 Aug 2020 16:03:34
User entered empty.	System	22 Aug 2020 16:02:44



US3432242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Aug 2020 16:03:34
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	22 Aug 2020 16:03:34
User entered missing code ND - Not Done; reason for change Data Entry Error	Phoebe Cunningham (b) (4)	22 Aug 2020 16:03:34
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Aug 2020 16:02:44
User entered empty.	Phoebe Cunningham (b) (4)	22 Aug 2020 16:02:44

US3432242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User entered 'mmHg'	System	22 Aug 2020 16:03:34
User entered empty.	System	22 Aug 2020 16:02:44

US3432242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Aug 2020 16:03:34
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	22 Aug 2020 16:03:34
User entered missing code ND - Not Done; reason for change Data Entry Error	Phoebe Cunningham (b) (4)	22 Aug 2020 16:03:34
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Aug 2020 16:02:44
User entered empty.	Phoebe Cunningham (b) (4)	22 Aug 2020 16:02:44

US3432242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User entered 'mmHg'	System	22 Aug 2020 16:03:34
User entered empty.	System	22 Aug 2020 16:02:44

US3432242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55

US3432242

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55

US3432242

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:37:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	22 Aug 2020 13:30:05

US3432242

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:37:31

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '22 Aug 2020'	Phoebe Cunningham (b) (4)	22 Aug 2020 13:30:05



US3432242

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:31

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:04:15

US3432242

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:31

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'No (N)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:04:15

US3432242

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:31

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'No (N)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:04:15

US3432242

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:31

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'No (N)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:04:15

US3432242

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:31

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'No (N)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:04:15

US3432242

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:31

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'No (N)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:04:15

US3432242

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:31

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'No (N)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:04:15

US3432242

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:31

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'No (N)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:04:15



US3432242

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:31

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'No (N)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:04:15

US3432242

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:31

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'No (N)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:04:15

US3432242

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:31

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'No (N)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:04:15

US3432242

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:31

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'No (N)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:04:15

US3432242

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:31

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	Phoebe Cunningham (b) (4)	22 Aug 2020 16:04:15

US3432242

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:31

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '0'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:04:15

US3432242

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:31

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '0'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:04:15

US3432242

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:31

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '0'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:04:15



US3432242

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:31

**Resides in high density housing** (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '0'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:04:15

US3432242

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:31

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '0'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:04:15

US3432242

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:31

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'I'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:04:15

US3432242

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:31

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '0'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:04:15

US3432242

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:37:31

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:39:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	Phoebe Cunningham (b) (4)	22 Aug 2020 16:04:15

US3432242

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:37:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	22 Aug 2020 13:29:42

US3432242

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:37:31

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '22 Aug 2020'	Phoebe Cunningham (b) (4)	22 Aug 2020 13:29:42

US3432242

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:37:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Clinic (Clinic)'	Phoebe Cunningham (b) (4)	22 Aug 2020 13:29:42



US3432242

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:37:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'VISIT1'	System	22 Aug 2020 13:29:42

US3432242

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:37:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '22 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 12:59:12

US3432242

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:37:31

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '187775'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 12:59:12

US3432242

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:37:31

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Aug 2020 12:59:12

US3432242

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:37:31

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'No (N)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:04:55

US3432242

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:37:31

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'No (N)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:04:55

US3432242

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:37:31

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'No (N)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:04:55

US3432242

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:37:31

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'No (N)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:04:55



US3432242

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:37:31

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'No (N)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:04:55

US3432242

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:37:31

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 14:32:51
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:39:05
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:17:01

US3432242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:37:31

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	22 Aug 2020 16:37:45

US3432242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:37:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	22 Aug 2020 16:37:45

US3432242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:37:31

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	22 Aug 2020 16:37:45

US3432242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:37:31

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	22 Aug 2020 16:37:45

US3432242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User accepted default value 'Pre-Dose (PREDOSE)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:37:45

US3432242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:37:45



US3432242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '22 Aug 2020'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:37:45

US3432242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:31

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '8:45'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:37:45

US3432242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered '22 Aug 2020 8:45'	System	22 Aug 2020 16:37:45

US3432242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '37' C	Phoebe Cunningham (b) (4)	22 Aug 2020 16:37:45

US3432242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Oral (Oral)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:37:45

US3432242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	Phoebe Cunningham (b) (4)	22 Aug 2020 16:37:45

US3432242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '59'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:37:45

US3432242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'bpm'	System	22 Aug 2020 16:37:45



US3432242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '16'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:37:45

US3432242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'breaths/min'	System	22 Aug 2020 16:37:45

US3432242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '149'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:37:45

US3432242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'mmHg'	System	22 Aug 2020 16:37:45

US3432242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '72'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:37:45

US3432242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'mmHg'	System	22 Aug 2020 16:37:45

US3432242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:37:31

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	22 Aug 2020 16:37:45

US3432242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:37:31

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	22 Aug 2020 16:37:45



US3432242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User accepted default value 'Post-Dose (POSTDOSE)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:37:45

US3432242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:37:45

US3432242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '22 Aug 2020'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:37:45

US3432242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:31

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '10:07'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:37:45

US3432242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered '22 Aug 2020 10:07'	System	22 Aug 2020 16:37:45

US3432242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '36.8' C	Phoebe Cunningham (b) (4)	22 Aug 2020 16:37:45

US3432242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Oral (Oral)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:37:45

US3432242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	Phoebe Cunningham (b) (4)	22 Aug 2020 16:37:45



US3432242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '51'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:37:45

US3432242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'bpm'	System	22 Aug 2020 16:37:45

US3432242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '16'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:37:45

US3432242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'breaths/min'	System	22 Aug 2020 16:37:45

US3432242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	24 Aug 2020 10:34:24
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Pre-dose pressure 149 - not significant increase' (Site from System).	Phoebe Cunningham (b) (4)	22 Aug 2020 17:23:33
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	22 Aug 2020 16:37:45
User entered '156'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:37:45

US3432242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'mmHg'	System	22 Aug 2020 16:37:45

US3432242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '75'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:37:45

US3432242

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'mmHg'	System	22 Aug 2020 16:37:45



US3432242

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:37:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'No (N)'	Phoebe Cunningham (b) (4)	22 Aug 2020 13:29:48

US3432242

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:37:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	Phoebe Cunningham (b) (4)	22 Aug 2020 13:29:48

US3432242

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:37:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	22 Aug 2020 13:43:33

US3432242

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:37:31

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	Phoebe Cunningham (b) (4)	22 Aug 2020 13:43:33

US3432242

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:37:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	Phoebe Cunningham (b) (4)	22 Aug 2020 13:43:33

US3432242

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:37:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'MRNA-1273 OR PLACEBO'	System	22 Aug 2020 13:43:33

US3432242

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:37:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '22 Aug 2020'	Phoebe Cunningham (b) (4)	22 Aug 2020 13:43:33

US3432242

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:37:31

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '9:32'	Phoebe Cunningham (b) (4)	22 Aug 2020 13:43:33



US3432242

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:37:31

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered '22 Aug 2020 9:32'	System	22 Aug 2020 13:43:33

US3432242

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:37:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Left Arm (LEFT ARM)'	Phoebe Cunningham (b) (4)	22 Aug 2020 13:43:33

US3432242

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:37:31

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'ONCE'	System	22 Aug 2020 13:43:33

US3432242

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:37:31

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'INTRAMUSCULAR'	System	22 Aug 2020 13:43:33

US3432242

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:10:39

US3432242

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '22 Aug 2020'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:10:39

US3432242

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '9:10'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:10:39

US3432242

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered '22 Aug 2020 9:10'	System	22 Aug 2020 16:10:39



US3432242

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:37:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '22 Aug 2020'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:10:53

US3432242

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:37:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:10:53

US3432242

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:37:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:10:53

US3432242

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:37:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '09:16'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:10:53

**US3432242**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:37:31**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered '22 Aug 2020 09:16'	System	22 Aug 2020 16:10:53

US3432242

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:37:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:10:53

US3432242

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:37:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'No (N)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:10:53

US3432242

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:37:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	Phoebe Cunningham (b) (4)	22 Aug 2020 16:10:53



**US3432242**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:37:31**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered empty.	System	22 Aug 2020 16:10:53

US3432242

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:37:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:10:59

US3432242

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:37:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'I'	System	22 Aug 2020 16:10:59

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	22 Aug 2020 13:43:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-22T10:16:54', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '8a9a606a-a37e-4d90-b4cd-1dee46d45a9b' User entered 'Yes (Y)'	System	22 Aug 2020 14:17:29
	System	22 Aug 2020 14:17:29

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-22T10:17:04', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '8a9a606a-a37e-4d90-b4cd-1dee46d45a9b' User entered '98.3'	System	22 Aug 2020 14:17:29
	System	22 Aug 2020 14:17:29

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-22T10:17:15', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '8a9a606a-a37e-4d90-b4cd-1dee46d45a9b' User entered 'No (N)'	System	22 Aug 2020 14:17:29
	System	22 Aug 2020 14:17:29

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-22T10:17:25', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '8a9a606a-a37e-4d90-b4cd-1dee46d45a9b' User entered '22 Aug 2020 10:17'	System	22 Aug 2020 14:17:29
	System	22 Aug 2020 14:17:29



US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '22 Aug 2020 09:52'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '22 Aug 2020 12:22'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	22 Aug 2020 13:43:33
User entered 'Day 1, after vaccination (at home)'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-23T10:05:15', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '8d9d2db4-7d6a-4d05-8bbb-a54409ba8332'	System	23 Aug 2020 14:05:34
User entered 'Yes (Y)'	System	23 Aug 2020 14:05:34

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-23T10:05:23', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '8d9d2db4-7d6a-4d05-8bbb-a54409ba8332' User entered '97.4'	System	23 Aug 2020 14:05:34
	System	23 Aug 2020 14:05:34

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-23T10:05:27', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '8d9d2db4-7d6a-4d05-8bbb-a54409ba8332'	System	23 Aug 2020 14:05:34
User entered 'No (N)'	System	23 Aug 2020 14:05:34

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-23T10:05:32', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '8d9d2db4-7d6a-4d05-8bbb-a54409ba8332'	System	23 Aug 2020 14:05:34
User entered '23 Aug 2020 10:05'	System	23 Aug 2020 14:05:34

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '22 Aug 2020 13:17'	System	22 Aug 2020 13:43:33



US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '23 Aug 2020 11:59'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	22 Aug 2020 13:43:33
User entered 'Day 2'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:37:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-24T07:33:02', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '5cffa681-42f9-4a14-9d94-a46459fcfac2'	System	24 Aug 2020 11:33:18
User entered 'Yes (Y)'	System	24 Aug 2020 11:33:18

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:37:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-24T07:33:08', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '5cffa681-42f9-4a14-9d94-a46459fcfac2' User entered '97.5'	System	24 Aug 2020 11:33:18
	System	24 Aug 2020 11:33:18

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:37:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-24T07:33:12', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '5cffa681-42f9-4a14-9d94-a46459fcfac2'	System	24 Aug 2020 11:33:18
User entered 'No (N)'	System	24 Aug 2020 11:33:18

**US3432242**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:37:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-24T07:33:17', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '5cffa681-42f9-4a14-9d94-a46459fcfac2'	System	24 Aug 2020 11:33:18
User entered '24 Aug 2020 07:33'	System	24 Aug 2020 11:33:18

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 13:43:33



US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	22 Aug 2020 13:43:33
User entered 'Day 3'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:37:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-25T08:18:04', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '9573ebe3-e07f-467c-a7d2-660ba59955e4' User entered 'Yes (Y)'	System	25 Aug 2020 12:18:18
	System	25 Aug 2020 12:18:18

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:37:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-25T08:18:09', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '9573ebe3-e07f-467c-a7d2-660ba59955e4' User entered '97.3'	System	25 Aug 2020 12:18:18
	System	25 Aug 2020 12:18:18

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:37:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-25T08:18:13', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '9573ebe3-e07f-467c-a7d2-660ba59955e4' User entered 'No (N)'	System	25 Aug 2020 12:18:18
	System	25 Aug 2020 12:18:18

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:37:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-25T08:18:17', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '9573ebe3-e07f-467c-a7d2-660ba59955e4' User entered '25 Aug 2020 08:18'	System	25 Aug 2020 12:18:18
	System	25 Aug 2020 12:18:18

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	22 Aug 2020 13:43:33
User entered 'Day 4'	System	22 Aug 2020 13:43:33



US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:37:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-26T08:07:06', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'ce5edae7-4e16-497e-95e2-0af2e6160d3c' User entered 'Yes (Y)'	System	26 Aug 2020 12:07:22
	System	26 Aug 2020 12:07:22

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:37:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-26T08:07:13', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'ce5edae7-4e16-497e-95e2-0af2e6160d3c' User entered '97.2'	System	26 Aug 2020 12:07:22
	System	26 Aug 2020 12:07:22

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:37:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-26T08:07:16', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'ce5edae7-4e16-497e-95e2-0af2e6160d3c'	System	26 Aug 2020 12:07:22
User entered 'No (N)'	System	26 Aug 2020 12:07:22

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:37:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-26T08:07:20', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'ce5edae7-4e16-497e-95e2-0af2e6160d3c' User entered '26 Aug 2020 08:07'	System	26 Aug 2020 12:07:22
	System	26 Aug 2020 12:07:22

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '25 Aug 2020 12:00'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '26 Aug 2020 11:59'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	22 Aug 2020 13:43:33
User entered 'Day 5'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:37:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-27T08:23:38', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '2e65aded-2bc6-4c9a-9851-0a6437007240' User entered 'Yes (Y)'	System	27 Aug 2020 12:23:57
	System	27 Aug 2020 12:23:57



US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:37:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-27T08:23:44', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '2e65aded-2bc6-4c9a-9851-0a6437007240' User entered '97.2'	System	27 Aug 2020 12:23:57
	System	27 Aug 2020 12:23:57

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:37:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-27T08:23:47', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '2e65aded-2bc6-4c9a-9851-0a6437007240' User entered 'No (N)'	System	27 Aug 2020 12:23:57
	System	27 Aug 2020 12:23:57

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:37:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-27T08:23:53', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '2e65aded-2bc6-4c9a-9851-0a6437007240' User entered '27 Aug 2020 08:23'	System	27 Aug 2020 12:23:57
	System	27 Aug 2020 12:23:57

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '26 Aug 2020 12:00'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '27 Aug 2020 11:59'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	22 Aug 2020 13:43:33
User entered 'Day 6'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:37:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-28T07:37:40', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '9087ef0e-f2e5-44a6-a627-b007fef78a41' User entered 'Yes (Y)'	System	28 Aug 2020 11:37:56
	System	28 Aug 2020 11:37:56

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:37:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-28T07:37:46', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '9087ef0e-f2e5-44a6-a627-b007fef78a41' User entered '96.0'	System	28 Aug 2020 11:37:56
	System	28 Aug 2020 11:37:56



US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:37:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-28T07:37:50', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '9087ef0e-f2e5-44a6-a627-b007fef78a41'	System	28 Aug 2020 11:37:56
User entered 'No (N)'	System	28 Aug 2020 11:37:56

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:37:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-28T07:37:54', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '9087ef0e-f2e5-44a6-a627-b007fef78a41' User entered '28 Aug 2020 07:37'	System	28 Aug 2020 11:37:56
	System	28 Aug 2020 11:37:56

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '27 Aug 2020 12:00'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '28 Aug 2020 11:59'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	22 Aug 2020 13:43:33
User entered 'Day 7'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:37:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-29T10:06:41', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '7c2d6f0c-5682-47fd-bac7-618935c14586' User entered 'Yes (Y)'	System	29 Aug 2020 14:07:01
	System	29 Aug 2020 14:07:01

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:37:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-29T10:06:49', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '7c2d6f0c-5682-47fd-bac7-618935c14586' User entered '98.0'	System	29 Aug 2020 14:07:01
	System	29 Aug 2020 14:07:01

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:37:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-29T10:06:52', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '7c2d6f0c-5682-47fd-bac7-618935c14586'	System	29 Aug 2020 14:07:01
User entered 'No (N)'	System	29 Aug 2020 14:07:01



US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:37:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-29T10:06:57', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '7c2d6f0c-5682-47fd-bac7-618935c14586'	System	29 Aug 2020 14:07:01
User entered '29 Aug 2020 10:06'	System	29 Aug 2020 14:07:01

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '28 Aug 2020 12:00'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '29 Aug 2020 11:59'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	22 Aug 2020 13:43:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-22T10:18:27', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '66e7c865-c9c9-43e3-bac6-eaa097477962'	System	22 Aug 2020 14:18:36
User entered 'None (1)'	System	22 Aug 2020 14:18:36

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-22T10:18:06', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '66e7c865-c9c9-43e3-bac6-eaa097477962'	System	22 Aug 2020 14:18:36
User entered 'No (N)'	System	22 Aug 2020 14:18:36

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-22T10:18:10', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '66e7c865-c9c9-43e3-bac6-eaa097477962'	System	22 Aug 2020 14:18:36
User entered 'No (N)'	System	22 Aug 2020 14:18:36

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-22T10:18:18', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '66e7c865-c9c9-43e3-bac6-eaa097477962' User entered 'None (1)'	System	22 Aug 2020 14:18:36
	System	22 Aug 2020 14:18:36



US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-22T10:18:32', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '66e7c865-c9c9-43e3-bac6-eaa097477962'	System	22 Aug 2020 14:18:36
User entered '22 Aug 2020 10:18'	System	22 Aug 2020 14:18:36

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '22 Aug 2020 09:52'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '22 Aug 2020 12:22'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	22 Aug 2020 13:43:33
User entered 'Day 1, after vaccination (at home)'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-23T10:05:44', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '91f0529e-dca0-4f09-819b-64c99eb60da8'	System	23 Aug 2020 14:07:45
User entered 'Does not interfere with activity (2)'	System	23 Aug 2020 14:07:45

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-23T10:05:47', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '91f0529e-dca0-4f09-819b-64c99eb60da8' User entered 'No (N)'	System	23 Aug 2020 14:07:45
	System	23 Aug 2020 14:07:45

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-23T10:05:51', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '91f0529e-dca0-4f09-819b-64c99eb60da8' User entered 'Yes (Y)'	System	23 Aug 2020 14:07:45
	System	23 Aug 2020 14:07:45

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

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)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-23T10:07:19', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '91f0529e-dca0-4f09-819b-64c99eb60da8' User entered '1'	System	23 Aug 2020 14:07:45
	System	23 Aug 2020 14:07:45



US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-23T10:07:36', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '91f0529e-dca0-4f09-819b-64c99eb60da8' User entered 'None (1)'	System	23 Aug 2020 14:07:45
	System	23 Aug 2020 14:07:45

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-23T10:07:43', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '91f0529e-dca0-4f09-819b-64c99eb60da8' User entered '23 Aug 2020 10:07'	System	23 Aug 2020 14:07:45
	System	23 Aug 2020 14:07:45

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '22 Aug 2020 13:17'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '23 Aug 2020 11:59'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	22 Aug 2020 13:43:33
User entered 'Day 2'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:37:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-24T07:33:28', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '9082ceb2-9ec3-4bf4-be37-6ef35e11006e'	System	24 Aug 2020 11:34:24
User entered 'Does not interfere with activity (2)'	System	24 Aug 2020 11:34:24

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:37:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-24T07:33:55', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '9082ceb2-9ec3-4bf4-be37-6ef35e11006e' User entered 'No (N)'	System	24 Aug 2020 11:34:24
	System	24 Aug 2020 11:34:24

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:37:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-24T07:34:00', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '9082ceb2-9ec3-4bf4-be37-6ef35e11006e' User entered 'Yes (Y)'	System	24 Aug 2020 11:34:24
	System	24 Aug 2020 11:34:24



US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:37:31

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)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-24T07:34:10', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '9082ceb2-9ec3-4bf4-be37-6ef35e11006e' User entered '1'	System	24 Aug 2020 11:34:24
	System	24 Aug 2020 11:34:24

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:37:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-24T07:34:16', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '9082ceb2-9ec3-4bf4-be37-6ef35e11006e' User entered 'None (1)'	System	24 Aug 2020 11:34:24
	System	24 Aug 2020 11:34:24

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:37:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-24T07:34:22', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '9082ceb2-9ec3-4bf4-be37-6ef35e11006e' User entered '24 Aug 2020 07:34'	System	24 Aug 2020 11:34:24
	System	24 Aug 2020 11:34:24

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	22 Aug 2020 13:43:33
User entered 'Day 3'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:37:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-25T08:18:22', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '00d8fa67-a653-47e8-9a84-78c46e13cfd2'	System	25 Aug 2020 12:18:41
User entered 'None (1)'	System	25 Aug 2020 12:18:41

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:37:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-25T08:18:25', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '00d8fa67-a653-47e8-9a84-78c46e13cfd2'	System	25 Aug 2020 12:18:41
User entered 'No (N)'	System	25 Aug 2020 12:18:41



US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:37:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-25T08:18:30', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '00d8fa67-a653-47e8-9a84-78c46e13cfd2'	System	25 Aug 2020 12:18:41
User entered 'No (N)'	System	25 Aug 2020 12:18:41

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:37:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-25T08:18:33', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '00d8fa67-a653-47e8-9a84-78c46e13cfd2'	System	25 Aug 2020 12:18:41
User entered 'None (1)'	System	25 Aug 2020 12:18:41

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:37:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-25T08:18:36', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '00d8fa67-a653-47e8-9a84-78c46e13cfd2'	System	25 Aug 2020 12:18:41
User entered '25 Aug 2020 08:18'	System	25 Aug 2020 12:18:41

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	22 Aug 2020 13:43:33
User entered 'Day 4'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:37:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-26T08:07:27', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'f96c8e1a-8db1-41a3-909c-759070255a03' User entered 'None (1)'	System	26 Aug 2020 12:07:47
	System	26 Aug 2020 12:07:47

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:37:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-26T08:07:31', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'f96c8e1a-8db1-41a3-909c-759070255a03' User entered 'No (N)'	System	26 Aug 2020 12:07:47
	System	26 Aug 2020 12:07:47



US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:37:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-26T08:07:34', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'f96c8e1a-8db1-41a3-909c-759070255a03' User entered 'No (N)'	System	26 Aug 2020 12:07:47
	System	26 Aug 2020 12:07:47

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:37:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-26T08:07:39', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'f96c8e1a-8db1-41a3-909c-759070255a03' User entered 'None (1)'	System	26 Aug 2020 12:07:47
	System	26 Aug 2020 12:07:47

**US3432242**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:37:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-26T08:07:43', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'f96c8e1a-8db1-41a3-909c-759070255a03' User entered '26 Aug 2020 08:07'	System	26 Aug 2020 12:07:47
	System	26 Aug 2020 12:07:47

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '25 Aug 2020 12:00'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '26 Aug 2020 11:59'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	22 Aug 2020 13:43:33
User entered 'Day 5'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:37:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-27T08:23:57', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'cc7148d3-3aff-4fef-89b2-4d2bea3d039d' User entered 'None (1)'	System	27 Aug 2020 12:24:13
	System	27 Aug 2020 12:24:13

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:37:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-27T08:24:02', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'cc7148d3-3aff-4fef-89b2-4d2bea3d039d' User entered 'No (N)'	System	27 Aug 2020 12:24:13
	System	27 Aug 2020 12:24:13



US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:37:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-27T08:24:04', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'cc7148d3-3aff-4fef-89b2-4d2bea3d039d' User entered 'No (N)'	System	27 Aug 2020 12:24:13
	System	27 Aug 2020 12:24:13

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:37:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-27T08:24:08', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'cc7148d3-3aff-4fef-89b2-4d2bea3d039d' User entered 'None (1)'	System	27 Aug 2020 12:24:13
	System	27 Aug 2020 12:24:13

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:37:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-27T08:24:11', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'cc7148d3-3aff-4fef-89b2-4d2bea3d039d' User entered '27 Aug 2020 08:24'	System	27 Aug 2020 12:24:13
	System	27 Aug 2020 12:24:13

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '26 Aug 2020 12:00'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '27 Aug 2020 11:59'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	22 Aug 2020 13:43:33
User entered 'Day 6'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:37:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-28T07:38:01', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'd275d2bf-28ec-41fd-8733-f188a1427d51' User entered 'None (1)'	System	28 Aug 2020 11:38:27
	System	28 Aug 2020 11:38:27

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:37:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-28T07:38:05', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'd275d2bf-28ec-41fd-8733-f188a1427d51'	System	28 Aug 2020 11:38:27
User entered 'No (N)'	System	28 Aug 2020 11:38:27



US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:37:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-28T07:38:13', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'd275d2bf-28ec-41fd-8733-f188a1427d51'	System	28 Aug 2020 11:38:27
User entered 'No (N)'	System	28 Aug 2020 11:38:27

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:37:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-28T07:38:21', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'd275d2bf-28ec-41fd-8733-f188a1427d51'	System	28 Aug 2020 11:38:27
User entered 'None (1)'	System	28 Aug 2020 11:38:27

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:37:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-28T07:38:24', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'd275d2bf-28ec-41fd-8733-f188a1427d51' User entered '28 Aug 2020 07:38'	System	28 Aug 2020 11:38:27
	System	28 Aug 2020 11:38:27

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '27 Aug 2020 12:00'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '28 Aug 2020 11:59'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	22 Aug 2020 13:43:33
User entered 'Day 7'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:37:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-29T10:07:02', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'd59e375b-a19d-4166-b3e3-5936eb318ae5' User entered 'None (1)'	System	29 Aug 2020 14:07:18
	System	29 Aug 2020 14:07:18

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:37:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-29T10:07:05', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'd59e375b-a19d-4166-b3e3-5936eb318ae5' User entered 'No (N)'	System	29 Aug 2020 14:07:18
	System	29 Aug 2020 14:07:18



US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:37:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-29T10:07:08', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'd59e375b-a19d-4166-b3e3-5936eb318ae5' User entered 'No (N)'	System	29 Aug 2020 14:07:18
	System	29 Aug 2020 14:07:18

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:37:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-29T10:07:12', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'd59e375b-a19d-4166-b3e3-5936eb318ae5' User entered 'None (1)'	System	29 Aug 2020 14:07:18
	System	29 Aug 2020 14:07:18

**US3432242**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:37:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-29T10:07:16', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'd59e375b-a19d-4166-b3e3-5936eb318ae5' User entered '29 Aug 2020 10:07'	System	29 Aug 2020 14:07:18
	System	29 Aug 2020 14:07:18

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '28 Aug 2020 12:00'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '29 Aug 2020 11:59'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	22 Aug 2020 13:43:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-22T10:18:39', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'e5cf49f0-fc6c-41b8-87d1-37484e4f570b' User entered 'None (0)'	System	22 Aug 2020 14:19:07
	System	22 Aug 2020 14:19:07

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-22T10:18:43', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'e5cf49f0-fc6c-41b8-87d1-37484e4f570b' User entered 'None (0)'	System	22 Aug 2020 14:19:07
	System	22 Aug 2020 14:19:07



US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-22T10:18:46', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'e5cf49f0-fc6c-41b8-87d1-37484e4f570b' User entered 'None (0)'	System	22 Aug 2020 14:19:07
	System	22 Aug 2020 14:19:07

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-22T10:18:49', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'e5cf49f0-fc6c-41b8-87d1-37484e4f570b' User entered 'None (0)'	System	22 Aug 2020 14:19:07
	System	22 Aug 2020 14:19:07

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-22T10:18:52', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'e5cf49f0-fc6c-41b8-87d1-37484e4f570b' User entered 'None (0)'	System	22 Aug 2020 14:19:07
	System	22 Aug 2020 14:19:07

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-22T10:18:55', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'e5cf49f0-fc6c-41b8-87d1-37484e4f570b' User entered 'None (0)'	System	22 Aug 2020 14:19:07
	System	22 Aug 2020 14:19:07

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-22T10:19:00', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'e5cf49f0-fc6c-41b8-87d1-37484e4f570b'	System	22 Aug 2020 14:19:07
User entered 'No (N)'	System	22 Aug 2020 14:19:07

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-22T10:19:04', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'e5cf49f0-fc6c-41b8-87d1-37484e4f570b' User entered '22 Aug 2020 10:19'	System	22 Aug 2020 14:19:07
	System	22 Aug 2020 14:19:07

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '22 Aug 2020 09:52'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '22 Aug 2020 12:22'	System	22 Aug 2020 13:43:33



US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	22 Aug 2020 13:43:33
User entered 'Day 1, after vaccination (at home)'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-23T10:07:49', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '96b1724e-79d0-4f72-8f96-d05e6bcd7d85' User entered 'None (0)'	System	23 Aug 2020 14:08:19
	System	23 Aug 2020 14:08:19

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-23T10:07:55', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '96b1724e-79d0-4f72-8f96-d05e6bcd7d85'	System	23 Aug 2020 14:08:19
User entered 'No interference with activity (1)'	System	23 Aug 2020 14:08:19

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-23T10:07:59', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '96b1724e-79d0-4f72-8f96-d05e6bcd7d85' User entered 'None (0)'	System	23 Aug 2020 14:08:19
	System	23 Aug 2020 14:08:19

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-23T10:08:03', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '96b1724e-79d0-4f72-8f96-d05e6bcd7d85' User entered 'None (0)'	System	23 Aug 2020 14:08:19
	System	23 Aug 2020 14:08:19

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-23T10:08:06', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '96b1724e-79d0-4f72-8f96-d05e6bcd7d85' User entered 'None (0)'	System	23 Aug 2020 14:08:19
	System	23 Aug 2020 14:08:19

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-23T10:08:09', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '96b1724e-79d0-4f72-8f96-d05e6bcd7d85' User entered 'None (0)'	System	23 Aug 2020 14:08:19
	System	23 Aug 2020 14:08:19

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-23T10:08:12', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '96b1724e-79d0-4f72-8f96-d05e6bcd7d85' User entered 'No (N)'	System	23 Aug 2020 14:08:19
	System	23 Aug 2020 14:08:19



US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-23T10:08:18', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '96b1724e-79d0-4f72-8f96-d05e6bcd7d85' User entered '23 Aug 2020 10:08'	System	23 Aug 2020 14:08:19
	System	23 Aug 2020 14:08:19

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '22 Aug 2020 13:17'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '23 Aug 2020 11:59'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	22 Aug 2020 13:43:33
User entered 'Day 2'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:37:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-24T07:34:28', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '5c39598a-2978-43f1-84db-bfdc0609185b' User entered 'None (0)'	System	24 Aug 2020 11:35:07
	System	24 Aug 2020 11:35:07

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:37:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-24T07:34:35', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '5c39598a-2978-43f1-84db-bfdc0609185b' User entered 'None (0)'	System	24 Aug 2020 11:35:07
	System	24 Aug 2020 11:35:07

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:37:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-24T07:34:42', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '5c39598a-2978-43f1-84db-bfdc0609185b'	System	24 Aug 2020 11:35:07
User entered 'No interference with activity (1)'	System	24 Aug 2020 11:35:07

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:37:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-24T07:34:51', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '5c39598a-2978-43f1-84db-bfdc0609185b'	System	24 Aug 2020 11:35:07
User entered 'No interference with activity (1)'	System	24 Aug 2020 11:35:07



US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:37:31

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-24T07:34:54', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '5c39598a-2978-43f1-84db-bfdc0609185b' User entered 'None (0)'	System	24 Aug 2020 11:35:07
	System	24 Aug 2020 11:35:07

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:37:31

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-24T07:34:56', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '5c39598a-2978-43f1-84db-bfdc0609185b' User entered 'None (0)'	System	24 Aug 2020 11:35:07
	System	24 Aug 2020 11:35:07

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:37:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-24T07:35:02', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '5c39598a-2978-43f1-84db-bfdc0609185b' User entered 'No (N)'	System	24 Aug 2020 11:35:07
	System	24 Aug 2020 11:35:07

**US3432242**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:37:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-24T07:35:05', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '5c39598a-2978-43f1-84db-bfdc0609185b' User entered '24 Aug 2020 07:35'	System	24 Aug 2020 11:35:07
	System	24 Aug 2020 11:35:07

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '23 Aug 2020 12:00'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '24 Aug 2020 11:59'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	22 Aug 2020 13:43:33
User entered 'Day 3'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:37:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-25T08:18:42', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'b4d68a0f-bbca-4440-85ab-52a1df689712' User entered 'None (0)'	System	25 Aug 2020 12:19:10
	System	25 Aug 2020 12:19:10



US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:37:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-25T08:18:46', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'b4d68a0f-bbca-4440-85ab-52a1df689712' User entered 'None (0)'	System	25 Aug 2020 12:19:10
	System	25 Aug 2020 12:19:10

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:37:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-25T08:18:50', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'b4d68a0f-bbca-4440-85ab-52a1df689712' User entered 'None (0)'	System	25 Aug 2020 12:19:10
	System	25 Aug 2020 12:19:10

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:37:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-25T08:18:56', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'b4d68a0f-bbca-4440-85ab-52a1df689712'	System	25 Aug 2020 12:19:10
User entered 'No interference with activity (1)'	System	25 Aug 2020 12:19:10

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:37:31

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-25T08:18:59', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'b4d68a0f-bbca-4440-85ab-52a1df689712' User entered 'None (0)'	System	25 Aug 2020 12:19:10
	System	25 Aug 2020 12:19:10

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:37:31

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-25T08:19:01', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'b4d68a0f-bbca-4440-85ab-52a1df689712' User entered 'None (0)'	System	25 Aug 2020 12:19:10
	System	25 Aug 2020 12:19:10

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:37:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-25T08:19:05', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'b4d68a0f-bbca-4440-85ab-52a1df689712'	System	25 Aug 2020 12:19:10
User entered 'No (N)'	System	25 Aug 2020 12:19:10

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:37:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-25T08:19:08', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'b4d68a0f-bbca-4440-85ab-52a1df689712' User entered '25 Aug 2020 08:19'	System	25 Aug 2020 12:19:10
	System	25 Aug 2020 12:19:10

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '24 Aug 2020 12:00'	System	22 Aug 2020 13:43:33



US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '25 Aug 2020 11:59'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	22 Aug 2020 13:43:33
User entered 'Day 4'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:37:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-26T08:07:49', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'e796aa09-4376-44a6-9af9-92c4cb16ef71' User entered 'None (0)'	System	26 Aug 2020 12:08:20
	System	26 Aug 2020 12:08:20

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:37:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-26T08:07:54', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'e796aa09-4376-44a6-9af9-92c4cb16ef71'	System	26 Aug 2020 12:08:20
User entered 'Some interference with activity (2)'	System	26 Aug 2020 12:08:20

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:37:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-26T08:08:01', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'e796aa09-4376-44a6-9af9-92c4cb16ef71' User entered 'None (0)'	System	26 Aug 2020 12:08:20
	System	26 Aug 2020 12:08:20

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:37:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-26T08:08:06', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'e796aa09-4376-44a6-9af9-92c4cb16ef71'	System	26 Aug 2020 12:08:20
User entered 'No interference with activity (1)'	System	26 Aug 2020 12:08:20

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:37:31

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-26T08:08:09', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'e796aa09-4376-44a6-9af9-92c4cb16ef71' User entered 'None (0)'	System	26 Aug 2020 12:08:20
	System	26 Aug 2020 12:08:20

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:37:31

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-26T08:08:12', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'e796aa09-4376-44a6-9af9-92c4cb16ef71' User entered 'None (0)'	System	26 Aug 2020 12:08:20
	System	26 Aug 2020 12:08:20



US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:37:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-26T08:08:14', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'e796aa09-4376-44a6-9af9-92c4cb16ef71'	System	26 Aug 2020 12:08:20
User entered 'No (N)'	System	26 Aug 2020 12:08:20

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:37:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-26T08:08:17', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'e796aa09-4376-44a6-9af9-92c4cb16ef71' User entered '26 Aug 2020 08:08'	System	26 Aug 2020 12:08:20
	System	26 Aug 2020 12:08:20

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '25 Aug 2020 12:00'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '26 Aug 2020 11:59'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	22 Aug 2020 13:43:33
User entered 'Day 5'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:37:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-27T08:24:16', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '0c1fb091-42d9-4342-b038-1ea4e01cef81' User entered 'None (0)'	System	27 Aug 2020 12:24:47
	System	27 Aug 2020 12:24:47

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:37:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-27T08:24:22', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '0c1fb091-42d9-4342-b038-1ea4e01cef81' User entered 'None (0)'	System	27 Aug 2020 12:24:47
	System	27 Aug 2020 12:24:47

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:37:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-27T08:24:27', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '0c1fb091-42d9-4342-b038-1ea4e01cef81' User entered 'None (0)'	System	27 Aug 2020 12:24:47
	System	27 Aug 2020 12:24:47



US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:37:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-27T08:24:34', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '0c1fb091-42d9-4342-b038-1ea4e01cef81'	System	27 Aug 2020 12:24:47
User entered 'No interference with activity (1)'	System	27 Aug 2020 12:24:47

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:37:31

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-27T08:24:37', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '0c1fb091-42d9-4342-b038-1ea4e01cef81' User entered 'None (0)'	System	27 Aug 2020 12:24:47
	System	27 Aug 2020 12:24:47

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:37:31

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-27T08:24:40', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '0c1fb091-42d9-4342-b038-1ea4e01cef81' User entered 'None (0)'	System	27 Aug 2020 12:24:47
	System	27 Aug 2020 12:24:47

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:37:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-27T08:24:43', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '0c1fb091-42d9-4342-b038-1ea4e01cef81' User entered 'No (N)'	System	27 Aug 2020 12:24:47
	System	27 Aug 2020 12:24:47

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:37:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-27T08:24:45', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '0c1fb091-42d9-4342-b038-1ea4e01cef81' User entered '27 Aug 2020 08:24'	System	27 Aug 2020 12:24:47
	System	27 Aug 2020 12:24:47

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '26 Aug 2020 12:00'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '27 Aug 2020 11:59'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	22 Aug 2020 13:43:33
User entered 'Day 6'	System	22 Aug 2020 13:43:33



US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:37:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-28T07:38:29', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '3fdb3c1a-6164-44b3-bdda-771ddcc7aa87' User entered 'None (0)'	System	28 Aug 2020 11:38:59
	System	28 Aug 2020 11:38:59

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:37:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-28T07:38:34', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '3fdb3c1a-6164-44b3-bdda-771ddcc7aa87' User entered 'None (0)'	System	28 Aug 2020 11:38:59
	System	28 Aug 2020 11:38:59

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:37:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-28T07:38:41', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '3fdb3c1a-6164-44b3-bdda-771ddcc7aa87' User entered 'None (0)'	System	28 Aug 2020 11:38:59
	System	28 Aug 2020 11:38:59

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:37:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-28T07:38:44', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '3fdb3c1a-6164-44b3-bdda-771ddcc7aa87'	System	28 Aug 2020 11:38:59
User entered 'No interference with activity (1)'	System	28 Aug 2020 11:38:59

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:37:31

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-28T07:38:47', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '3fdb3c1a-6164-44b3-bdda-771ddcc7aa87' User entered 'None (0)'	System	28 Aug 2020 11:38:59
	System	28 Aug 2020 11:38:59

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:37:31

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-28T07:38:49', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '3fdb3c1a-6164-44b3-bdda-771ddcc7aa87' User entered 'None (0)'	System	28 Aug 2020 11:38:59
	System	28 Aug 2020 11:38:59

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:37:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-28T07:38:52', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '3fdb3c1a-6164-44b3-bdda-771ddcc7aa87'	System	28 Aug 2020 11:38:59
User entered 'No (N)'	System	28 Aug 2020 11:38:59

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:37:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-28T07:38:56', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '3fdb3c1a-6164-44b3-bdda-771ddcc7aa87' User entered '28 Aug 2020 07:38'	System	28 Aug 2020 11:38:59
	System	28 Aug 2020 11:38:59



US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '27 Aug 2020 12:00'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '28 Aug 2020 11:59'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	22 Aug 2020 13:43:33
User entered 'Day 7'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:37:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-29T10:07:21', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '83e0b9f7-9e06-4d41-917b-39c1b9f36ee6' User entered 'None (0)'	System	29 Aug 2020 14:07:53
	System	29 Aug 2020 14:07:53

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:37:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-29T10:07:24', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '83e0b9f7-9e06-4d41-917b-39c1b9f36ee6' User entered 'None (0)'	System	29 Aug 2020 14:07:53
	System	29 Aug 2020 14:07:53

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:37:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-29T10:07:28', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '83e0b9f7-9e06-4d41-917b-39c1b9f36ee6' User entered 'None (0)'	System	29 Aug 2020 14:07:53
	System	29 Aug 2020 14:07:53

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:37:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-29T10:07:31', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '83e0b9f7-9e06-4d41-917b-39c1b9f36ee6'	System	29 Aug 2020 14:07:53
User entered 'No interference with activity (1)'	System	29 Aug 2020 14:07:53

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:37:31

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-29T10:07:37', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '83e0b9f7-9e06-4d41-917b-39c1b9f36ee6' User entered 'None (0)'	System	29 Aug 2020 14:07:53
	System	29 Aug 2020 14:07:53



US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:37:31

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-29T10:07:40', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '83e0b9f7-9e06-4d41-917b-39c1b9f36ee6' User entered 'None (0)'	System	29 Aug 2020 14:07:53
	System	29 Aug 2020 14:07:53

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:37:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-29T10:07:43', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '83e0b9f7-9e06-4d41-917b-39c1b9f36ee6'	System	29 Aug 2020 14:07:53
User entered 'No (N)'	System	29 Aug 2020 14:07:53

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:37:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-08-29T10:07:48', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '83e0b9f7-9e06-4d41-917b-39c1b9f36ee6' User entered '29 Aug 2020 10:07'	System	29 Aug 2020 14:07:53
	System	29 Aug 2020 14:07:53

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '28 Aug 2020 12:00'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '29 Aug 2020 11:59'	System	22 Aug 2020 13:43:33

US3432242

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	28 Aug 2020 11:38:59
User entered 'Day 8'	System	28 Aug 2020 11:38:59

US3432242

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 17:37:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 17:37:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50



US3432242

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 11:38:59

US3432242

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(8)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 11:38:59

US3432242

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	29 Aug 2020 14:07:53
User entered 'Day 9'	System	29 Aug 2020 14:07:53

US3432242

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 09 Jun 2021 17:37:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 09 Jun 2021 17:37:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 14:07:53

US3432242

Folder: Diary Dose 1 (1)

Form: JointsAche\_Day(9)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 14:07:53

US3432242

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	28 Aug 2020 11:38:59
User entered 'Day 8'	System	28 Aug 2020 11:38:59



US3432242

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:37:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:37:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 11:38:59

US3432242

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 11:38:59

US3432242

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	29 Aug 2020 14:07:53
User entered 'Day 9'	System	29 Aug 2020 14:07:53

US3432242

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 17:37:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 17:37:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 14:07:53



US3432242

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 14:07:53

US3432242

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	29 Aug 2020 19:28:16

US3432242

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '29 Aug 2020'	Julia Klopfer (b) (4)	29 Aug 2020 19:28:16

US3432242

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Contact Made (CONTACT MADE)'	Julia Klopfer (b) (4)	29 Aug 2020 19:28:16

US3432242

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:31

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	Julia Klopfer (b) (4)	29 Aug 2020 19:28:16

US3432242

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	29 Aug 2020 19:28:23

US3432242

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'I'	System	29 Aug 2020 19:28:23

US3432242

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	05 Sep 2020 17:18:50



US3432242

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '05 Sep 2020' reason for change: Per Query Resolution	Xhoi Mitre (b) (4)	10 Nov 2020 15:10:35
User entered '5 Sep 2020'	Phoebe Cunningham (b) (4)	05 Sep 2020 17:18:50

US3432242

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	05 Sep 2020 17:18:50

US3432242

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:31

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	Phoebe Cunningham (b) (4)	05 Sep 2020 17:18:50

US3432242

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	05 Sep 2020 17:20:32

US3432242

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'I'	System	05 Sep 2020 17:20:32

US3432242

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	14 Sep 2020 21:36:11

US3432242

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '14 Sep 2020'	Phoebe Cunningham (b) (4)	14 Sep 2020 21:36:11

US3432242

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	14 Sep 2020 21:36:11



US3432242

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:31

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	Phoebe Cunningham (b) (4)	14 Sep 2020 21:36:11

US3432242

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	Jessica Cauley (b) (4)	21 Sep 2020 13:07:07

US3432242

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'I'	System	21 Sep 2020 13:07:07

US3432242

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:37:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	Jessica Cauley (b) (4)	21 Sep 2020 13:08:03

US3432242

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:37:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '21 Sep 2020'	Jessica Cauley (b) (4)	21 Sep 2020 13:08:03

US3432242

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:37:31

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Clinic (Clinic)'	Jessica Cauley (b) (4)	21 Sep 2020 13:08:03

**US3432242**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:37:31**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'VISIT2'	System	21 Sep 2020 13:08:03

US3432242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	21 Sep 2020 14:30:13



US3432242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:31

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 14:30:13

US3432242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 14:30:13

US3432242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:31

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '8:17'	(b) (4), (b) (6)	21 Sep 2020 14:30:13

US3432242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered '21 Sep 2020 8:17'	System	21 Sep 2020 14:30:13

US3432242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '98.3' F	(b) (4), (b) (6)	21 Sep 2020 14:30:13

US3432242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Oral (Oral)'	(b) (4), (b) (6)	21 Sep 2020 14:30:13

US3432242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 14:30:13

US3432242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '58'	(b) (4), (b) (6)	21 Sep 2020 14:30:13



US3432242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'bpm'	System	21 Sep 2020 14:30:13

US3432242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '16'	(b) (4), (b) (6)	21 Sep 2020 14:30:13

US3432242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'breaths/min'	System	21 Sep 2020 14:30:13

US3432242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '156'	(b) (4), (b) (6)	21 Sep 2020 14:30:13

US3432242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'mmHg'	System	21 Sep 2020 14:30:13

US3432242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '75'	(b) (4), (b) (6)	21 Sep 2020 14:30:13

US3432242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:37:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'mmHg'	System	21 Sep 2020 14:30:13

US3432242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	21 Sep 2020 14:30:13



US3432242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 14:30:13

US3432242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 14:30:13

US3432242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:31

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '9:30'	(b) (4), (b) (6)	21 Sep 2020 14:30:13

US3432242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered '21 Sep 2020 9:30'	System	21 Sep 2020 14:30:13

US3432242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '97.9' F	(b) (4), (b) (6)	21 Sep 2020 14:30:13

US3432242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Oral (Oral)'	(b) (4), (b) (6)	21 Sep 2020 14:30:13

US3432242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 14:30:13

US3432242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '51'	(b) (4), (b) (6)	21 Sep 2020 14:30:13



US3432242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'bpm'	System	21 Sep 2020 14:30:13

US3432242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '16'	(b) (4), (b) (6)	21 Sep 2020 14:30:13

US3432242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'breaths/min'	System	21 Sep 2020 14:30:13

US3432242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '166'	(b) (4), (b) (6)	21 Sep 2020 14:30:13

US3432242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'mmHg'	System	21 Sep 2020 14:30:13

US3432242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '81'	(b) (4), (b) (6)	21 Sep 2020 14:30:13

US3432242

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:37:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'mmHg'	System	21 Sep 2020 14:30:13

US3432242

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:37:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 14:24:32



US3432242

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:37:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 14:24:32

US3432242

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:37:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	Jessica Cauley (b) (4)	21 Sep 2020 13:08:41

US3432242

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:37:31

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	Jessica Cauley (b) (4)	21 Sep 2020 13:08:41

US3432242

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:37:31

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	Jessica Cauley (b) (4)	21 Sep 2020 13:08:41

US3432242

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:37:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'MRNA-1273 OR PLACEBO'	System	21 Sep 2020 13:08:41

US3432242

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:37:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '21 Sep 2020'	Jessica Cauley (b) (4)	21 Sep 2020 13:08:41

US3432242

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:37:31

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '08:58'	Jessica Cauley (b) (4)	21 Sep 2020 13:08:41

US3432242

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:37:31

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered '21 Sep 2020 08:58'	System	21 Sep 2020 13:08:41



US3432242

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:37:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Left Arm (LEFT ARM)'	Jessica Cauley (b) (4)	21 Sep 2020 13:08:41

US3432242

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:37:31

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'ONCE'	System	21 Sep 2020 13:08:41

US3432242

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:37:31

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'INTRAMUSCULAR'	System	21 Sep 2020 13:08:41

US3432242

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	Jessica Cauley (b) (4)	21 Sep 2020 17:33:57

US3432242

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '21 Sep 2020'	Jessica Cauley (b) (4)	21 Sep 2020 17:33:57

US3432242

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '08:35'	Jessica Cauley (b) (4)	21 Sep 2020 17:33:57

US3432242

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered '21 Sep 2020 08:35'	System	21 Sep 2020 17:33:57

US3432242

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:37:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '21 Sep 2020'	Jessica Cauley (b) (4)	21 Sep 2020 17:34:08



US3432242

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:37:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jessica Cauley (b) (4) (b) (4)	21 Sep 2020 17:34:08

US3432242

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:37:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	Jessica Cauley (b) (4)	21 Sep 2020 17:34:08

US3432242

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:37:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '08:43'	Jessica Cauley (b) (4)	21 Sep 2020 17:34:08

**US3432242**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:37:31**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered '21 Sep 2020 08:43'	System	21 Sep 2020 17:34:08

US3432242

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:37:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jessica Cauley (b) (4) (b) (4)	21 Sep 2020 17:34:08

US3432242

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:37:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'No (N)'	Jessica Cauley (b) (4)	21 Sep 2020 17:34:08

US3432242

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:37:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	Jessica Cauley (b) (4)	21 Sep 2020 17:34:08

US3432242

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:37:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered empty.	System	21 Sep 2020 17:34:08



US3432242

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 14:24:24

US3432242

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'I'	System	21 Sep 2020 14:24:24

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	21 Sep 2020 13:08:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-21T09:34:41', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '069139cd-b097-46af-8999-c04b1610473b' User entered 'Yes (Y)'	System	21 Sep 2020 13:35:08
	System	21 Sep 2020 13:35:08

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-21T09:34:53', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '069139cd-b097-46af-8999-c04b1610473b' User entered '97.9'	System	21 Sep 2020 13:35:08
	System	21 Sep 2020 13:35:08

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-21T09:34:59', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '069139cd-b097-46af-8999-c04b1610473b' User entered 'No (N)'	System	21 Sep 2020 13:35:08
	System	21 Sep 2020 13:35:08

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-21T09:35:05', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '069139cd-b097-46af-8999-c04b1610473b' User entered '21 Sep 2020 09:35'	System	21 Sep 2020 13:35:08
	System	21 Sep 2020 13:35:08

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '21 Sep 2020 09:18'	System	21 Sep 2020 13:08:41



US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '21 Sep 2020 11:48'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	21 Sep 2020 13:08:41
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-22T07:32:32', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '909ca4fa-330b-4501-9e7a-38d5ee3138d2' User entered 'Yes (Y)'	System	22 Sep 2020 11:33:17
	System	22 Sep 2020 11:33:17

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-22T07:32:47', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '909ca4fa-330b-4501-9e7a-38d5ee3138d2' User entered '101.7'	System	22 Sep 2020 11:33:17
	System	22 Sep 2020 11:33:17

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-22T07:32:52', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '909ca4fa-330b-4501-9e7a-38d5ee3138d2'	System	22 Sep 2020 11:33:17
User entered 'Yes (Y)'	System	22 Sep 2020 11:33:17

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
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 'contacted at safety call' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 07:59:27
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Monica Feeley (b) (4)	10 Nov 2020 21:41:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-22T07:33:02', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '909ca4fa-330b-4501-9e7a-38d5ee3138d2'	System	22 Sep 2020 11:33:17
User entered '1'	System	22 Sep 2020 11:33:17

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-22T07:33:02', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '909ca4fa-330b-4501-9e7a-38d5ee3138d2' User entered '0'	System	22 Sep 2020 11:33:17
	System	22 Sep 2020 11:33:17

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-22T07:33:15', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '909ca4fa-330b-4501-9e7a-38d5ee3138d2' User entered '22 Sep 2020 07:33'	System	22 Sep 2020 11:33:17
	System	22 Sep 2020 11:33:17



US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '21 Sep 2020 12:43'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	21 Sep 2020 13:08:41
User entered 'Day 2'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:37:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-23T09:09:27', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'c9c4baa3-c404-41d9-81fb-113a49c1c151' User entered 'Yes (Y)'	System	23 Sep 2020 13:10:00
	System	23 Sep 2020 13:10:00

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:37:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-23T09:09:42', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'c9c4baa3-c404-41d9-81fb-113a49c1c151' User entered '98.4'	System	23 Sep 2020 13:10:00
	System	23 Sep 2020 13:10:00

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:37:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-23T09:09:49', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'c9c4baa3-c404-41d9-81fb-113a49c1c151' User entered 'No (N)'	System	23 Sep 2020 13:10:00
	System	23 Sep 2020 13:10:00

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:37:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-23T09:09:55', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'c9c4baa3-c404-41d9-81fb-113a49c1c151' User entered '23 Sep 2020 09:09'	System	23 Sep 2020 13:10:00
	System	23 Sep 2020 13:10:00

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 13:08:41



US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	21 Sep 2020 13:08:41
User entered 'Day 3'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:37:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:37:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:37:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:37:31

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:37:31

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:37:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50



US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	21 Sep 2020 13:08:41
User entered 'Day 4'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:37:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-24T18:38:23', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '6e616eb8-7743-4073-9569-45ee6c0d4fb2' User entered 'Yes (Y)'	System	24 Sep 2020 22:38:41
	System	24 Sep 2020 22:38:41

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:37:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-24T18:38:30', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '6e616eb8-7743-4073-9569-45ee6c0d4fb2' User entered '98.4'	System	24 Sep 2020 22:38:41
	System	24 Sep 2020 22:38:41

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:37:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-24T18:38:35', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '6e616eb8-7743-4073-9569-45ee6c0d4fb2'	System	24 Sep 2020 22:38:41
User entered 'No (N)'	System	24 Sep 2020 22:38:41

**US3432242**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 17:37:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-24T18:38:39', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '6e616eb8-7743-4073-9569-45ee6c0d4fb2' User entered '24 Sep 2020 18:38'	System	24 Sep 2020 22:38:41
	System	24 Sep 2020 22:38:41

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 13:08:41



US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	21 Sep 2020 13:08:41
User entered 'Day 5'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:37:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-26T10:04:12', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '96e5d6bd-b387-40de-af74-6c82990f6324' User entered 'Yes (Y)'	System	26 Sep 2020 14:04:25
	System	26 Sep 2020 14:04:25

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:37:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-26T10:04:16', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '96e5d6bd-b387-40de-af74-6c82990f6324' User entered '97.6'	System	26 Sep 2020 14:04:25
	System	26 Sep 2020 14:04:25

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:37:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-26T10:04:19', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '96e5d6bd-b387-40de-af74-6c82990f6324' User entered 'No (N)'	System	26 Sep 2020 14:04:25
	System	26 Sep 2020 14:04:25

**US3432242**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:37:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-26T10:04:23', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '96e5d6bd-b387-40de-af74-6c82990f6324' User entered '26 Sep 2020 10:04'	System	26 Sep 2020 14:04:25
	System	26 Sep 2020 14:04:25

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 13:08:41



US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	21 Sep 2020 13:08:41
User entered 'Day 6'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:37:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-27T11:06:33', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '99619bf3-3d3e-4933-a0e8-17bd3eb03eb5' User entered 'Yes (Y)'	System	27 Sep 2020 15:06:49
	System	27 Sep 2020 15:06:49

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:37:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-27T11:06:40', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '99619bf3-3d3e-4933-a0e8-17bd3eb03eb5' User entered '97.2'	System	27 Sep 2020 15:06:49
	System	27 Sep 2020 15:06:49

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:37:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-27T11:06:42', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '99619bf3-3d3e-4933-a0e8-17bd3eb03eb5'	System	27 Sep 2020 15:06:49
User entered 'No (N)'	System	27 Sep 2020 15:06:49

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:37:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-27T11:06:46', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '99619bf3-3d3e-4933-a0e8-17bd3eb03eb5' User entered '27 Sep 2020 11:06'	System	27 Sep 2020 15:06:49
	System	27 Sep 2020 15:06:49

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	21 Sep 2020 13:08:41
User entered 'Day 7'	System	21 Sep 2020 13:08:41



US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:37:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:37:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:37:31

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:37:31

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:37:31

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:37:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 13:08:41



US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	21 Sep 2020 13:08:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-21T09:35:20', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'b0f86978-73a0-495d-bae5-487e98dd3d8e' User entered 'None (1)'	System	21 Sep 2020 13:36:00
	System	21 Sep 2020 13:36:00

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-21T09:35:38', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'b0f86978-73a0-495d-bae5-487e98dd3d8e' User entered 'No (N)'	System	21 Sep 2020 13:36:00
	System	21 Sep 2020 13:36:00

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-21T09:35:48', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'b0f86978-73a0-495d-bae5-487e98dd3d8e' User entered 'No (N)'	System	21 Sep 2020 13:36:00
	System	21 Sep 2020 13:36:00

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-21T09:35:54', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'b0f86978-73a0-495d-bae5-487e98dd3d8e' User entered 'None (1)'	System	21 Sep 2020 13:36:00
	System	21 Sep 2020 13:36:00

**US3432242**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:37:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-21T09:35:57', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'b0f86978-73a0-495d-bae5-487e98dd3d8e' User entered '21 Sep 2020 09:35'	System	21 Sep 2020 13:36:00
	System	21 Sep 2020 13:36:00

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '21 Sep 2020 09:18'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '21 Sep 2020 11:48'	System	21 Sep 2020 13:08:41



US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	21 Sep 2020 13:08:41
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-22T07:33:41', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'd2fade66-5147-440e-afb0-bfa4aa3a33a7'	System	22 Sep 2020 11:36:19
User entered 'Does not interfere with activity (2)'	System	22 Sep 2020 11:36:19

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-22T07:35:05', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'd2fade66-5147-440e-afb0-bfa4aa3a33a7' User entered 'No (N)'	System	22 Sep 2020 11:36:19
	System	22 Sep 2020 11:36:19

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-22T07:35:15', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'd2fade66-5147-440e-afb0-bfa4aa3a33a7' User entered 'Yes (Y)'	System	22 Sep 2020 11:36:19
	System	22 Sep 2020 11:36:19

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

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)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-22T07:36:02', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'd2fade66-5147-440e-afb0-bfa4aa3a33a7' User entered '5'	System	22 Sep 2020 11:36:19
	System	22 Sep 2020 11:36:19

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-22T07:36:12', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'd2fade66-5147-440e-afb0-bfa4aa3a33a7' User entered 'None (1)'	System	22 Sep 2020 11:36:19
	System	22 Sep 2020 11:36:19

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-22T07:36:17', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'd2fade66-5147-440e-afb0-bfa4aa3a33a7' User entered '22 Sep 2020 07:36'	System	22 Sep 2020 11:36:19
	System	22 Sep 2020 11:36:19

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '21 Sep 2020 12:43'	System	21 Sep 2020 13:08:41



US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	21 Sep 2020 13:08:41
User entered 'Day 2'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:37:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-23T09:10:03', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '616aa104-997e-4a73-a867-3cfd60042e3d'	System	23 Sep 2020 13:10:21
User entered 'Does not interfere with activity (2)'	System	23 Sep 2020 13:10:21

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:37:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-23T09:10:07', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '616aa104-997e-4a73-a867-3cfd60042e3d' User entered 'No (N)'	System	23 Sep 2020 13:10:21
	System	23 Sep 2020 13:10:21

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:37:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-23T09:10:11', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '616aa104-997e-4a73-a867-3cfd60042e3d' User entered 'No (N)'	System	23 Sep 2020 13:10:21
	System	23 Sep 2020 13:10:21

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:37:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-23T09:10:15', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '616aa104-997e-4a73-a867-3cfd60042e3d' User entered 'None (1)'	System	23 Sep 2020 13:10:21
	System	23 Sep 2020 13:10:21

**US3432242**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:37:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-23T09:10:18', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '616aa104-997e-4a73-a867-3cfd60042e3d' User entered '23 Sep 2020 09:10'	System	23 Sep 2020 13:10:21
	System	23 Sep 2020 13:10:21

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 13:08:41



US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	21 Sep 2020 13:08:41
User entered 'Day 3'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:37:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:37:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:37:31

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)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:37:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:37:31

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)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:37:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50



US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:37:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	21 Sep 2020 13:08:41
User entered 'Day 4'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:37:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-24T18:38:48', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'f48851eb-8d1c-4423-9c67-60e426d783bd'	System	24 Sep 2020 22:39:03
User entered 'Does not interfere with activity (2)'	System	24 Sep 2020 22:39:03

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:37:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-24T18:38:51', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'f48851eb-8d1c-4423-9c67-60e426d783bd' User entered 'No (N)'	System	24 Sep 2020 22:39:03
	System	24 Sep 2020 22:39:03

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:37:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-24T18:38:54', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'f48851eb-8d1c-4423-9c67-60e426d783bd' User entered 'No (N)'	System	24 Sep 2020 22:39:03
	System	24 Sep 2020 22:39:03

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:37:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-24T18:38:57', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'f48851eb-8d1c-4423-9c67-60e426d783bd' User entered 'None (1)'	System	24 Sep 2020 22:39:03
	System	24 Sep 2020 22:39:03



**US3432242**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:37:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-24T18:38:59', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'f48851eb-8d1c-4423-9c67-60e426d783bd' User entered '24 Sep 2020 18:38'	System	24 Sep 2020 22:39:03
	System	24 Sep 2020 22:39:03

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	21 Sep 2020 13:08:41
User entered 'Day 5'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:37:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-26T10:04:28', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'dfe3f9dd-992d-4b08-9921-ed21f79fe3f5'	System	26 Sep 2020 14:04:41
User entered 'Does not interfere with activity (2)'	System	26 Sep 2020 14:04:41

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:37:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-26T10:04:31', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'dfe3f9dd-992d-4b08-9921-ed21f79fe3f5'	System	26 Sep 2020 14:04:41
User entered 'No (N)'	System	26 Sep 2020 14:04:41

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:37:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-26T10:04:33', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'dfe3f9dd-992d-4b08-9921-ed21f79fe3f5' User entered 'No (N)'	System	26 Sep 2020 14:04:41
	System	26 Sep 2020 14:04:41

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:37:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-26T10:04:37', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'dfe3f9dd-992d-4b08-9921-ed21f79fe3f5' User entered 'None (1)'	System	26 Sep 2020 14:04:41
	System	26 Sep 2020 14:04:41



US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:37:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-26T10:04:39', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'dfe3f9dd-992d-4b08-9921-ed21f79fe3f5' User entered '26 Sep 2020 10:04'	System	26 Sep 2020 14:04:41
	System	26 Sep 2020 14:04:41

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	21 Sep 2020 13:08:41
User entered 'Day 6'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:37:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-27T11:06:50', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '5f59e7a4-56b4-42e7-9b19-cc1db4abd708' User entered 'None (1)'	System	27 Sep 2020 15:08:27
	System	27 Sep 2020 15:08:27

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:37:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-27T11:06:53', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '5f59e7a4-56b4-42e7-9b19-cc1db4abd708' User entered 'No (N)'	System	27 Sep 2020 15:08:27
	System	27 Sep 2020 15:08:27

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:37:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-27T11:06:56', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '5f59e7a4-56b4-42e7-9b19-cc1db4abd708' User entered 'No (N)'	System	27 Sep 2020 15:08:27
	System	27 Sep 2020 15:08:27

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:37:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-27T11:06:59', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '5f59e7a4-56b4-42e7-9b19-cc1db4abd708' User entered 'None (1)'	System	27 Sep 2020 15:08:27
	System	27 Sep 2020 15:08:27



**US3432242**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:37:31**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-27T11:07:01', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '5f59e7a4-56b4-42e7-9b19-cc1db4abd708' User entered '27 Sep 2020 11:07'	System	27 Sep 2020 15:08:27
	System	27 Sep 2020 15:08:27

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	21 Sep 2020 13:08:41
User entered 'Day 7'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:37:31

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:37:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:37:31

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)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:37:31

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50



US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:37:31

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)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:37:31

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:37:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	21 Sep 2020 13:08:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-21T09:36:03', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'b66db681-2a59-4e5f-a434-00a611c837a0' User entered 'None (0)'	System	21 Sep 2020 13:36:28
	System	21 Sep 2020 13:36:28

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-21T09:36:06', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'b66db681-2a59-4e5f-a434-00a611c837a0' User entered 'None (0)'	System	21 Sep 2020 13:36:28
	System	21 Sep 2020 13:36:28



US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-21T09:36:10', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'b66db681-2a59-4e5f-a434-00a611c837a0' User entered 'None (0)'	System	21 Sep 2020 13:36:28
	System	21 Sep 2020 13:36:28

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-21T09:36:13', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'b66db681-2a59-4e5f-a434-00a611c837a0' User entered 'None (0)'	System	21 Sep 2020 13:36:28
	System	21 Sep 2020 13:36:28

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-21T09:36:15', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'b66db681-2a59-4e5f-a434-00a611c837a0' User entered 'None (0)'	System	21 Sep 2020 13:36:28
	System	21 Sep 2020 13:36:28

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-21T09:36:18', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'b66db681-2a59-4e5f-a434-00a611c837a0' User entered 'None (0)'	System	21 Sep 2020 13:36:28
	System	21 Sep 2020 13:36:28

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-21T09:36:22', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'b66db681-2a59-4e5f-a434-00a611c837a0' User entered 'No (N)'	System	21 Sep 2020 13:36:28
	System	21 Sep 2020 13:36:28

**US3432242**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:37:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-21T09:36:25', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'b66db681-2a59-4e5f-a434-00a611c837a0' User entered '21 Sep 2020 09:36'	System	21 Sep 2020 13:36:28
	System	21 Sep 2020 13:36:28

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '21 Sep 2020 09:18'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '21 Sep 2020 11:48'	System	21 Sep 2020 13:08:41



US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	21 Sep 2020 13:08:41
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-22T07:36:40', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '4bf0ecad-f531-4fcc-a74f-19798fc0e6e0'	System	22 Sep 2020 11:37:42
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	22 Sep 2020 11:37:42

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-22T07:36:49', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '4bf0ecad-f531-4fcc-a74f-19798fc0e6e0'	System	22 Sep 2020 11:37:42
User entered 'Significant; prevents daily activity (3)'	System	22 Sep 2020 11:37:42

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-22T07:36:57', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '4bf0ecad-f531-4fcc-a74f-19798fc0e6e0'	System	22 Sep 2020 11:37:42
User entered 'Significant; prevents daily activity (3)'	System	22 Sep 2020 11:37:42

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-22T07:37:01', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '4bf0ecad-f531-4fcc-a74f-19798fc0e6e0'	System	22 Sep 2020 11:37:42
User entered 'Significant; prevents daily activity (3)'	System	22 Sep 2020 11:37:42

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-22T07:37:21', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '4bf0ecad-f531-4fcc-a74f-19798fc0e6e0'	System	22 Sep 2020 11:37:42
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	22 Sep 2020 11:37:42

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-22T07:37:30', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '4bf0ecad-f531-4fcc-a74f-19798fc0e6e0'	System	22 Sep 2020 11:37:42
User entered 'Some interference with activity not requiring medical attention (2)'	System	22 Sep 2020 11:37:42

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-22T07:37:35', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '4bf0ecad-f531-4fcc-a74f-19798fc0e6e0'	System	22 Sep 2020 11:37:42
User entered 'No (N)'	System	22 Sep 2020 11:37:42



**US3432242**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:37:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-22T07:37:40', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '4bf0ecad-f531-4fcc-a74f-19798fc0e6e0' User entered '22 Sep 2020 07:37'	System	22 Sep 2020 11:37:42
	System	22 Sep 2020 11:37:42

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '21 Sep 2020 12:43'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	21 Sep 2020 13:08:41
User entered 'Day 2'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:37:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-23T09:10:28', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'be175fc2-1fa4-4b44-a811-47a871cad891'	System	23 Sep 2020 13:11:19
User entered 'No interference with activity (1)'	System	23 Sep 2020 13:11:19

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:37:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-23T09:10:34', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'be175fc2-1fa4-4b44-a811-47a871cad891'	System	23 Sep 2020 13:11:19
User entered 'Some interference with activity (2)'	System	23 Sep 2020 13:11:19

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:37:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-23T09:10:45', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'be175fc2-1fa4-4b44-a811-47a871cad891'	System	23 Sep 2020 13:11:19
User entered 'No interference with activity (1)'	System	23 Sep 2020 13:11:19

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:37:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-23T09:10:49', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'be175fc2-1fa4-4b44-a811-47a871cad891'	System	23 Sep 2020 13:11:19
User entered 'No interference with activity (1)'	System	23 Sep 2020 13:11:19



US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:37:31

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-23T09:10:53', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'be175fc2-1fa4-4b44-a811-47a871cad891' User entered 'None (0)'	System	23 Sep 2020 13:11:19
	System	23 Sep 2020 13:11:19

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:37:31

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-23T09:11:09', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'be175fc2-1fa4-4b44-a811-47a871cad891' User entered 'None (0)'	System	23 Sep 2020 13:11:19
	System	23 Sep 2020 13:11:19

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:37:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-23T09:11:12', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'be175fc2-1fa4-4b44-a811-47a871cad891' User entered 'No (N)'	System	23 Sep 2020 13:11:19
	System	23 Sep 2020 13:11:19

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:37:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-23T09:11:16', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'be175fc2-1fa4-4b44-a811-47a871cad891' User entered '23 Sep 2020 09:11'	System	23 Sep 2020 13:11:19
	System	23 Sep 2020 13:11:19

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	21 Sep 2020 13:08:41
User entered 'Day 3'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:37:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50



US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:37:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:37:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:37:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:37:31

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:37:31

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:37:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:37:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 13:08:41



US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	21 Sep 2020 13:08:41
User entered 'Day 4'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:37:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-24T18:39:18', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'e3447d00-e263-46e8-8392-965b92c841eb'	System	24 Sep 2020 22:39:50
User entered 'No interference with activity (1)'	System	24 Sep 2020 22:39:50

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:37:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-24T18:39:25', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'e3447d00-e263-46e8-8392-965b92c841eb' User entered 'None (0)'	System	24 Sep 2020 22:39:50
	System	24 Sep 2020 22:39:50

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:37:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-24T18:39:30', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'e3447d00-e263-46e8-8392-965b92c841eb' User entered 'None (0)'	System	24 Sep 2020 22:39:50
	System	24 Sep 2020 22:39:50

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:37:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-24T18:39:33', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'e3447d00-e263-46e8-8392-965b92c841eb' User entered 'None (0)'	System	24 Sep 2020 22:39:50
	System	24 Sep 2020 22:39:50

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:37:31

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-24T18:39:37', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'e3447d00-e263-46e8-8392-965b92c841eb' User entered 'None (0)'	System	24 Sep 2020 22:39:50
	System	24 Sep 2020 22:39:50

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:37:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-24T18:39:40', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'e3447d00-e263-46e8-8392-965b92c841eb' User entered 'None (0)'	System	24 Sep 2020 22:39:50
	System	24 Sep 2020 22:39:50



US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:37:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-24T18:39:43', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'e3447d00-e263-46e8-8392-965b92c841eb' User entered 'No (N)'	System	24 Sep 2020 22:39:50
	System	24 Sep 2020 22:39:50

**US3432242**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:37:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-24T18:39:46', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'e3447d00-e263-46e8-8392-965b92c841eb' User entered '24 Sep 2020 18:39'	System	24 Sep 2020 22:39:50
	System	24 Sep 2020 22:39:50

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	21 Sep 2020 13:08:41
User entered 'Day 5'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:37:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-26T10:04:45', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'ecfbffcf-5fce-489d-867e-218086050afe' User entered 'None (0)'	System	26 Sep 2020 14:05:14
	System	26 Sep 2020 14:05:14

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:37:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-26T10:04:48', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'ecfbffcf-5fce-489d-867e-218086050afe'	System	26 Sep 2020 14:05:14
User entered 'No interference with activity (1)'	System	26 Sep 2020 14:05:14

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:37:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-26T10:04:56', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'ecfbffcf-5fce-489d-867e-218086050afe' User entered 'None (0)'	System	26 Sep 2020 14:05:14
	System	26 Sep 2020 14:05:14



US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:37:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-26T10:05:01', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'ecfbffcf-5fce-489d-867e-218086050afe' User entered 'No interference with activity (1)'	System	26 Sep 2020 14:05:14
	System	26 Sep 2020 14:05:14

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:37:31

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-26T10:05:04', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'ecfbffcf-5fce-489d-867e-218086050afe' User entered 'None (0)'	System	26 Sep 2020 14:05:14
	System	26 Sep 2020 14:05:14

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:37:31

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-26T10:05:06', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'ecfbffcf-5fce-489d-867e-218086050afe' User entered 'None (0)'	System	26 Sep 2020 14:05:14
	System	26 Sep 2020 14:05:14

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:37:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-26T10:05:08', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'ecfbffcf-5fce-489d-867e-218086050afe' User entered 'No (N)'	System	26 Sep 2020 14:05:14
	System	26 Sep 2020 14:05:14

**US3432242**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:37:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-26T10:05:11', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'ecfbffcf-5fce-489d-867e-218086050afe' User entered '26 Sep 2020 10:05'	System	26 Sep 2020 14:05:14
	System	26 Sep 2020 14:05:14

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	21 Sep 2020 13:08:41
User entered 'Day 6'	System	21 Sep 2020 13:08:41



US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:37:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-27T11:07:06', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '6ead0ed6-9550-44e5-b5dd-82305f152f1b' User entered 'None (0)'	System	27 Sep 2020 15:08:27
	System	27 Sep 2020 15:08:27

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:37:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-27T11:07:08', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '6ead0ed6-9550-44e5-b5dd-82305f152f1b' User entered 'None (0)'	System	27 Sep 2020 15:08:27
	System	27 Sep 2020 15:08:27

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:37:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-27T11:07:10', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '6ead0ed6-9550-44e5-b5dd-82305f152f1b' User entered 'None (0)'	System	27 Sep 2020 15:08:27
	System	27 Sep 2020 15:08:27

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:37:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-27T11:07:12', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '6ead0ed6-9550-44e5-b5dd-82305f152f1b' User entered 'None (0)'	System	27 Sep 2020 15:08:27
	System	27 Sep 2020 15:08:27

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:37:31

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-27T11:07:14', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '6ead0ed6-9550-44e5-b5dd-82305f152f1b' User entered 'None (0)'	System	27 Sep 2020 15:08:27
	System	27 Sep 2020 15:08:27

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:37:31

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-27T11:07:16', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '6ead0ed6-9550-44e5-b5dd-82305f152f1b' User entered 'None (0)'	System	27 Sep 2020 15:08:27
	System	27 Sep 2020 15:08:27

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:37:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-27T11:07:18', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '6ead0ed6-9550-44e5-b5dd-82305f152f1b' User entered 'No (N)'	System	27 Sep 2020 15:08:27
	System	27 Sep 2020 15:08:27

**US3432242**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:37:31**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-09-27T11:07:21', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '6ead0ed6-9550-44e5-b5dd-82305f152f1b' User entered '27 Sep 2020 11:07'	System	27 Sep 2020 15:08:27
	System	27 Sep 2020 15:08:27



US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:37:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	21 Sep 2020 13:08:41
User entered 'Day 7'	System	21 Sep 2020 13:08:41

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:37:31

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:37:31

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:37:31

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:37:31

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:37:31

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50



US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:37:31

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:37:31

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:37:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50

US3432242

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:37:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 13:08:41

**US3432242**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:37:31**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 13:08:41

US3432242

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Sep 2020 18:39:10

US3432242

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '28 Sep 2020'	(b) (4), (b) (6)	28 Sep 2020 18:39:10

US3432242

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	28 Sep 2020 18:39:10



US3432242

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:31

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	(b) (4), (b) (6)	28 Sep 2020 18:39:10

US3432242

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 12:45:41

US3432242

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'I'	System	06 Oct 2020 12:45:41

US3432242

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	07 Oct 2020 14:23:28

US3432242

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '7 Oct 2020'	Kathleen Garvey (b) (4)	07 Oct 2020 14:23:28

US3432242

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Contact Made (CONTACT MADE)'	Kathleen Garvey (b) (4)	07 Oct 2020 14:23:28

US3432242

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:31

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	Kathleen Garvey (b) (4)	07 Oct 2020 14:23:28

US3432242

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	07 Oct 2020 14:23:33



US3432242

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'I'	System	07 Oct 2020 14:23:33

US3432242

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 14:37:47

US3432242

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 14:37:47

US3432242

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	13 Oct 2020 14:37:47

US3432242

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:31

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 14:37:47

US3432242

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 14:38:22

US3432242

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'I'	System	13 Oct 2020 14:38:22

US3432242

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:37:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 20:25:45



US3432242

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:37:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '23 Oct 2020'	(b) (4), (b) (6)	23 Oct 2020 20:25:45

US3432242

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:37:31

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	23 Oct 2020 20:25:45

**US3432242**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:37:31**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'VISIT3'	System	23 Oct 2020 20:25:45

US3432242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 20:27:51

US3432242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '23 Oct 2020'	(b) (4), (b) (6)	23 Oct 2020 20:27:51

US3432242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '08:06'	(b) (4), (b) (6)	23 Oct 2020 20:27:51

US3432242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered '23 Oct 2020 08:06'	System	23 Oct 2020 20:27:51

US3432242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '97.1' F	(b) (4), (b) (6)	23 Oct 2020 20:27:51



US3432242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Other (Other)'	(b) (4), (b) (6)	23 Oct 2020 20:27:51

US3432242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Infra-red'	(b) (4), (b) (6)	23 Oct 2020 20:27:51

US3432242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '58'	(b) (4), (b) (6)	23 Oct 2020 20:27:51

US3432242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'bpm'	System	23 Oct 2020 20:27:51

US3432242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '14'	(b) (4), (b) (6)	23 Oct 2020 20:27:51

US3432242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'breaths/min'	System	23 Oct 2020 20:27:51

US3432242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '126'	(b) (4), (b) (6)	23 Oct 2020 20:27:51

US3432242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'mmHg'	System	23 Oct 2020 20:27:51



US3432242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '065'	(b) (4), (b) (6)	23 Oct 2020 20:27:51

US3432242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'mmHg'	System	23 Oct 2020 20:27:51

US3432242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23

US3432242

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23

US3432242

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:37:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'No (N)'	(b) (4), (b) (6)	23 Oct 2020 20:27:59

US3432242

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:37:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 20:27:59

US3432242

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 20:29:37

US3432242

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '23 Oct 2020'	(b) (4), (b) (6)	23 Oct 2020 20:29:37



US3432242

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '08:33'	(b) (4), (b) (6)	23 Oct 2020 20:29:37

**US3432242**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:37:31**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered '23 Oct 2020 08:33'	System	23 Oct 2020 20:29:37

US3432242

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 20:29:43

**US3432242**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:37:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'I'	System	23 Oct 2020 20:29:43

US3432242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	22 Aug 2020 13:43:33
User entered 'Day 64'	System	22 Aug 2020 13:43:33

US3432242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-10-22T11:33:52', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '49efbbaa-e216-473d-8aba-208181049705'	System	22 Oct 2020 15:34:48
User entered 'Yes (Y)'	System	22 Oct 2020 15:34:48

US3432242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-10-22T11:34:05', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '49efbbaa-e216-473d-8aba-208181049705'	System	22 Oct 2020 15:34:48
User entered 'No (N)'	System	22 Oct 2020 15:34:48

US3432242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-10-22T11:34:10', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '49efbbaa-e216-473d-8aba-208181049705' User entered 'No (N)'	System	22 Oct 2020 15:34:48
	System	22 Oct 2020 15:34:48



US3432242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-10-22T11:34:17', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '49efbbaa-e216-473d-8aba-208181049705'	System	22 Oct 2020 15:34:48
User entered 'Yes (Y)'	System	22 Oct 2020 15:34:48

**US3432242**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-10-22T11:34:29', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '49efbbaa-e216-473d-8aba-208181049705'	System	22 Oct 2020 15:34:48
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Oct 2020 15:34:48

**US3432242**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-10-22T11:34:36', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '49efbbaa-e216-473d-8aba-208181049705' User entered '22 Oct 2020 11:34:36'	System	22 Oct 2020 15:34:48
	System	22 Oct 2020 15:34:48

US3432242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	22 Aug 2020 13:43:33
User entered '22 Oct 2020 00:01'	System	22 Aug 2020 13:43:33

**US3432242**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	22 Aug 2020 13:43:33
User entered '26 Oct 2020 23:59'	System	22 Aug 2020 13:43:33

US3432242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	22 Aug 2020 13:43:33
User entered 'Day 71'	System	22 Aug 2020 13:43:33

US3432242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-10-29T23:00:42', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '561f4e16-76e5-43db-aa2f-a8a8466623a6' User entered 'No (N)'	System	30 Oct 2020 03:00:53
	System	30 Oct 2020 03:00:53

US3432242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-10-29T23:00:46', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '561f4e16-76e5-43db-aa2f-a8a8466623a6'	System	30 Oct 2020 03:00:53
User entered 'No (N)'	System	30 Oct 2020 03:00:53



**US3432242**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-10-29T23:00:51', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '561f4e16-76e5-43db-aa2f-a8a8466623a6' User entered '29 Oct 2020 23:00:51'	System	30 Oct 2020 03:00:53
	System	30 Oct 2020 03:00:53

US3432242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	22 Aug 2020 13:43:33
User entered '29 Oct 2020 00:01'	System	22 Aug 2020 13:43:33

US3432242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	22 Aug 2020 13:43:33
User entered '02 Nov 2020 23:59'	System	22 Aug 2020 13:43:33

US3432242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	22 Aug 2020 13:43:33
User entered 'Day 78'	System	22 Aug 2020 13:43:33

US3432242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-11-05T11:34:40', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '60f0d42b-c3ad-4d40-ba55-f385eb9785ee' User entered 'No (N)'	System	05 Nov 2020 16:34:54
	System	05 Nov 2020 16:34:54

US3432242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-11-05T11:34:44', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '60f0d42b-c3ad-4d40-ba55-f385eb9785ee' User entered 'No (N)'	System	05 Nov 2020 16:34:54
	System	05 Nov 2020 16:34:54

**US3432242**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-11-05T11:34:48', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '60f0d42b-c3ad-4d40-ba55-f385eb9785ee' User entered '05 Nov 2020 11:34:48'	System	05 Nov 2020 16:34:54
	System	05 Nov 2020 16:34:54

US3432242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	22 Aug 2020 13:43:33
User entered '05 Nov 2020 00:01'	System	22 Aug 2020 13:43:33



**US3432242**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:49:50
Data entry locked.	System	22 Aug 2020 13:43:33
User entered '09 Nov 2020 23:59'	System	22 Aug 2020 13:43:33

US3432242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:31:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:30
Data entry locked.	System	22 Aug 2020 13:43:33
User entered 'Day 92'	System	22 Aug 2020 13:43:33

US3432242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:31:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:30

US3432242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:31:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:31:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:30

US3432242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:31:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:30

US3432242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

Fever (Temperature  $\geq$  100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:31:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:31:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:31:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:30

US3432242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:31:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:31:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:31:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:31:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:31:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:31:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:30

US3432242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:31:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:30



US3432242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:31:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:31:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:31:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:30

US3432242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:31:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:31:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:30

US3432242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:31:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:30

US3432242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:31:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:31:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:30



US3432242

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:31:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:31:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:31:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:31:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:30
Data entry locked.	System	22 Aug 2020 13:43:33
User entered '19 Nov 2020 00:01'	System	22 Aug 2020 13:43:33

**US3432242**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:31:07
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 01:11:30
Data entry locked.	System	22 Aug 2020 13:43:33
User entered '23 Nov 2020 23:59'	System	22 Aug 2020 13:43:33

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-11-19T22:02:50', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '0f8dffa7-4d07-43ad-9256-6113e8476c28'	System	20 Nov 2020 03:03:11
User entered 'No (N)'	System	20 Nov 2020 03:03:11

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-11-19T22:02:59', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '0f8dffa7-4d07-43ad-9256-6113e8476c28'	System	20 Nov 2020 03:03:11
User entered 'No (N)'	System	20 Nov 2020 03:03:11



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-11-19T22:03:04', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '0f8dffa7-4d07-43ad-9256-6113e8476c28' User entered '19 Nov 2020 22:03:04'	System	20 Nov 2020 03:03:11
	System	20 Nov 2020 03:03:11

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '16 Nov 2020 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '20 Nov 2020 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-11-26T18:06:37', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '2f077b0e-291b-4b85-9d5b-cfd615c4704a' User entered 'No (N)'	System	26 Nov 2020 23:06:48
	System	26 Nov 2020 23:06:48

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-11-26T18:06:41', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '2f077b0e-291b-4b85-9d5b-cfd615c4704a' User entered 'No (N)'	System	26 Nov 2020 23:06:48
	System	26 Nov 2020 23:06:48

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-11-26T18:06:45', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '2f077b0e-291b-4b85-9d5b-cfd615c4704a' User entered '26 Nov 2020 18:06:45'	System	26 Nov 2020 23:06:48
	System	26 Nov 2020 23:06:48

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '23 Nov 2020 00:01'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '27 Nov 2020 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-11-30T11:31:47', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'b0ce5b21-2fe0-4ad4-8bcf-f80d54ec6a27'	System	30 Nov 2020 16:31:56
User entered 'No (N)'	System	30 Nov 2020 16:31:56

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-11-30T11:31:50', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'b0ce5b21-2fe0-4ad4-8bcf-f80d54ec6a27'	System	30 Nov 2020 16:31:56
User entered 'No (N)'	System	30 Nov 2020 16:31:56

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-11-30T11:31:54', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'b0ce5b21-2fe0-4ad4-8bcf-f80d54ec6a27' User entered '30 Nov 2020 11:31:54'	System	30 Nov 2020 16:31:56
	System	30 Nov 2020 16:31:56

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '30 Nov 2020 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '04 Dec 2020 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-12-07T07:28:24', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '229a39d2-3ce7-4a67-a148-77e9a4a3d53e' User entered 'No (N)'	System	07 Dec 2020 12:28:39
	System	07 Dec 2020 12:28:39

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-12-07T07:28:29', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '229a39d2-3ce7-4a67-a148-77e9a4a3d53e' User entered 'No (N)'	System	07 Dec 2020 12:28:39
	System	07 Dec 2020 12:28:39

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-12-07T07:28:33', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '229a39d2-3ce7-4a67-a148-77e9a4a3d53e' User entered '07 Dec 2020 07:28:33'	System	07 Dec 2020 12:28:39
	System	07 Dec 2020 12:28:39

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '07 Dec 2020 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '11 Dec 2020 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-12-15T14:43:59', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '83b1f6c5-734b-4537-b863-1bf9492fbc7a' User entered 'No (N)'	System	15 Dec 2020 19:44:11
	System	15 Dec 2020 19:44:11

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-12-15T14:44:02', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '83b1f6c5-734b-4537-b863-1bf9492fbc7a' User entered 'No (N)'	System	15 Dec 2020 19:44:11
	System	15 Dec 2020 19:44:11



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-12-15T14:44:06', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '83b1f6c5-734b-4537-b863-1bf9492fbc7a' User entered '15 Dec 2020 14:44:06'	System	15 Dec 2020 19:44:11
	System	15 Dec 2020 19:44:11

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '14 Dec 2020 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '18 Dec 2020 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-12-21T13:39:42', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'dc83c302-7050-49f7-a180-35d2d2a4655f' User entered 'No (N)'	System	21 Dec 2020 18:39:52
	System	21 Dec 2020 18:39:52

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-12-21T13:39:46', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'dc83c302-7050-49f7-a180-35d2d2a4655f' User entered 'No (N)'	System	21 Dec 2020 18:39:52
	System	21 Dec 2020 18:39:52

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-12-21T13:39:49', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'dc83c302-7050-49f7-a180-35d2d2a4655f' User entered '21 Dec 2020 13:39:49'	System	21 Dec 2020 18:39:52
	System	21 Dec 2020 18:39:52

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '21 Dec 2020 00:01'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '25 Dec 2020 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-12-30T15:31:05', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '503f9367-966e-4789-af61-55e1ffd2ac13'	System	30 Dec 2020 20:31:17
User entered 'No (N)'	System	30 Dec 2020 20:31:17

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-12-30T15:31:09', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '503f9367-966e-4789-af61-55e1ffd2ac13'	System	30 Dec 2020 20:31:17
User entered 'No (N)'	System	30 Dec 2020 20:31:17

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2020-12-30T15:31:12', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '503f9367-966e-4789-af61-55e1ffd2ac13' User entered '30 Dec 2020 15:31:12'	System	30 Dec 2020 20:31:17
	System	30 Dec 2020 20:31:17

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '28 Dec 2020 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '01 Jan 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2021-01-04T07:35:52', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '73b51290-4794-4718-8e9e-34758ebabdf'	System	04 Jan 2021 12:36:03
User entered 'No (N)'	System	04 Jan 2021 12:36:03

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2021-01-04T07:35:56', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '73b51290-4794-4718-8e9e-34758ebabdfc' User entered 'No (N)'	System	04 Jan 2021 12:36:03

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2021-01-04T07:36:00', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '73b51290-4794-4718-8e9e-34758ebabdfc' User entered '04 Jan 2021 07:36:00'	System	04 Jan 2021 12:36:03
	System	04 Jan 2021 12:36:03

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '04 Jan 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '08 Jan 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2021-01-11T07:08:53', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '6c1a9129-bb5e-436f-9681-6d951702836c' User entered 'No (N)'	System	11 Jan 2021 12:09:06
	System	11 Jan 2021 12:09:06

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2021-01-11T07:08:58', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '6c1a9129-bb5e-436f-9681-6d951702836c' User entered 'No (N)'	System	11 Jan 2021 12:09:06
	System	11 Jan 2021 12:09:06



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2021-01-11T07:09:02', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '6c1a9129-bb5e-436f-9681-6d951702836c' User entered '11 Jan 2021 07:09:02'	System	11 Jan 2021 12:09:06
	System	11 Jan 2021 12:09:06

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '11 Jan 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '15 Jan 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2021-01-19T11:39:39', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '7b2cf94e-9cda-4f70-8468-68bb9ef1f7dd' User entered 'No (N)'	System	19 Jan 2021 16:39:48
	System	19 Jan 2021 16:39:48

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2021-01-19T11:39:43', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '7b2cf94e-9cda-4f70-8468-68bb9ef1f7dd'	System	19 Jan 2021 16:39:48
User entered 'No (N)'	System	19 Jan 2021 16:39:48

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2021-01-19T11:39:46', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '7b2cf94e-9cda-4f70-8468-68bb9ef1f7dd' User entered '19 Jan 2021 11:39:46'	System	19 Jan 2021 16:39:48
	System	19 Jan 2021 16:39:48

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '18 Jan 2021 00:01'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '22 Jan 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2021-01-26T11:38:26', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'f5500152-78c1-4b8f-afc4-3ad05844e6c2'	System	26 Jan 2021 16:38:57
User entered 'No (N)'	System	26 Jan 2021 16:38:57

US3432242

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:37:31

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2021-01-26T11:38:29', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'f5500152-78c1-4b8f-afc4-3ad05844e6c2'	System	26 Jan 2021 16:38:57
User entered 'No (N)'	System	26 Jan 2021 16:38:57

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2021-01-26T11:38:32', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'f5500152-78c1-4b8f-afc4-3ad05844e6c2'	System	26 Jan 2021 16:38:57
User entered '26 Jan 2021 11:38:32'	System	26 Jan 2021 16:38:57

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '25 Jan 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '29 Jan 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2021-02-04T16:41:54', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'abee0b5e-aabf-4e5f-83ab-210ddad52b23'	System	04 Feb 2021 21:42:04
User entered 'No (N)'	System	04 Feb 2021 21:42:04

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2021-02-04T16:41:58', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'abee0b5e-aabf-4e5f-83ab-210ddad52b23'	System	04 Feb 2021 21:42:04
User entered 'No (N)'	System	04 Feb 2021 21:42:04

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2021-02-04T16:42:01', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'abee0b5e-aabf-4e5f-83ab-210ddad52b23' User entered '04 Feb 2021 16:42:01'	System	04 Feb 2021 21:42:04
	System	04 Feb 2021 21:42:04

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '01 Feb 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '05 Feb 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2021-02-10T17:46:13', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'f93c77ee-f34b-48e2-8a53-616b27b09ef8' User entered 'No (N)'	System	10 Feb 2021 22:46:26

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2021-02-10T17:46:17', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'f93c77ee-f34b-48e2-8a53-616b27b09ef8' User entered 'No (N)'	System	10 Feb 2021 22:46:26



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2021-02-10T17:46:21', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'f93c77ee-f34b-48e2-8a53-616b27b09ef8' User entered '10 Feb 2021 17:46:21'	System	10 Feb 2021 22:46:26
	System	10 Feb 2021 22:46:26

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '08 Feb 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '12 Feb 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2021-02-17T06:59:37', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '76fdab1e-e3e2-4e6f-acfe-c4f54cf7d2d9'	System	17 Feb 2021 11:59:47
User entered 'No (N)'	System	17 Feb 2021 11:59:47

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2021-02-17T06:59:41', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '76fdab1e-e3e2-4e6f-acfe-c4f54cf7d2d9'	System	17 Feb 2021 11:59:47
User entered 'No (N)'	System	17 Feb 2021 11:59:47

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2021-02-17T06:59:45', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '76fdab1e-e3e2-4e6f-acfe-c4f54cf7d2d9' User entered '17 Feb 2021 06:59:45'	System	17 Feb 2021 11:59:47

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '15 Feb 2021 00:01'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '19 Feb 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2021-02-22T08:36:25', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '7b8e6f84-d411-476b-874b-b7eafad863c9' User entered 'No (N)'	System	22 Feb 2021 13:36:59
	System	22 Feb 2021 13:36:59

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2021-02-22T08:36:27', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '7b8e6f84-d411-476b-874b-b7eafad863c9'	System	22 Feb 2021 13:36:59
User entered 'No (N)'	System	22 Feb 2021 13:36:59

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2021-02-22T08:36:30', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '7b8e6f84-d411-476b-874b-b7eafad863c9' User entered '22 Feb 2021 08:36:30'	System	22 Feb 2021 13:36:59
	System	22 Feb 2021 13:36:59

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '22 Feb 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '26 Feb 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2021-03-02T13:31:06-05:00', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '3f0d42f7-2cd8-45c2-8cfb-89f7aaeaa975'	System	02 Mar 2021 18:31:30
User entered 'No (N)'	System	02 Mar 2021 18:31:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2021-03-02T13:31:12-05:00', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '3f0d42f7-2cd8-45c2-8cfb-89f7aaeaa975'	System	02 Mar 2021 18:31:30
User entered 'No (N)'	System	02 Mar 2021 18:31:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2021-03-02T13:31:25-05:00', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '3f0d42f7-2cd8-45c2-8cfb-89f7aaeaa975'	System	02 Mar 2021 18:31:30
User entered '02 Mar 2021 13:31:25'	System	02 Mar 2021 18:31:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '01 Mar 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '05 Mar 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '08 Mar 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '12 Mar 2021 23:59'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (513C9424-1E4C-4D44-A50E-7BF5F7EE0869)', Time: '2021-03-18T15:38:40-04:00', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'b2021af4-cff6-47a3-9f0e-6ade9db79958'	System	18 Mar 2021 19:38:50
User entered 'No (N)'	System	18 Mar 2021 19:38:50

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (513C9424-1E4C-4D44-A50E-7BF5F7EE0869)', Time: '2021-03-18T15:38:43-04:00', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'b2021af4-cff6-47a3-9f0e-6ade9db79958'	System	18 Mar 2021 19:38:50
User entered 'No (N)'	System	18 Mar 2021 19:38:50

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (513C9424-1E4C-4D44-A50E-7BF5F7EE0869)', Time: '2021-03-18T15:38:46-04:00', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'b2021af4-cff6-47a3-9f0e-6ade9db79958'	System	18 Mar 2021 19:38:50
User entered '18 Mar 2021 15:38:46'	System	18 Mar 2021 19:38:50

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '15 Mar 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '19 Mar 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (513C9424-1E4C-4D44-A50E-7BF5F7EE0869)', Time: '2021-03-25T20:49:01-04:00', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '510e2ef4-27e8-4d61-9c5d-5451bfb04766'	System	26 Mar 2021 00:49:10
User entered 'No (N)'	System	26 Mar 2021 00:49:10



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (513C9424-1E4C-4D44-A50E-7BF5F7EE0869)', Time: '2021-03-25T20:49:04-04:00', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '510e2ef4-27e8-4d61-9c5d-5451bfb04766'	System	26 Mar 2021 00:49:10
User entered 'No (N)'	System	26 Mar 2021 00:49:10

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (513C9424-1E4C-4D44-A50E-7BF5F7EE0869)', Time: '2021-03-25T20:49:07-04:00', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '510e2ef4-27e8-4d61-9c5d-5451bfb04766'	System	26 Mar 2021 00:49:10
User entered '25 Mar 2021 20:49:07'	System	26 Mar 2021 00:49:10

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '22 Mar 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '26 Mar 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (513C9424-1E4C-4D44-A50E-7BF5F7EE0869)', Time: '2021-03-29T08:54:05-04:00', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '812dc8e6-b66c-4441-bf8c-1d9736b8f04f'	System	29 Mar 2021 12:54:23
User entered 'No (N)'	System	29 Mar 2021 12:54:23

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (513C9424-1E4C-4D44-A50E-7BF5F7EE0869)', Time: '2021-03-29T08:54:15-04:00', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '812dc8e6-b66c-4441-bf8c-1d9736b8f04f'	System	29 Mar 2021 12:54:23
User entered 'No (N)'	System	29 Mar 2021 12:54:23

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (513C9424-1E4C-4D44-A50E-7BF5F7EE0869)', Time: '2021-03-29T08:54:18-04:00', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '812dc8e6-b66c-4441-bf8c-1d9736b8f04f' User entered '29 Mar 2021 08:54:18'	System	29 Mar 2021 12:54:23
	System	29 Mar 2021 12:54:23



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '29 Mar 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '02 Apr 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (513C9424-1E4C-4D44-A50E-7BF5F7EE0869)', Time: '2021-04-08T18:15:20-04:00', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '86224585-1f9b-40a2-a8c7-a754c223c6a5' User entered 'No (N)'	System	08 Apr 2021 22:16:25
	System	08 Apr 2021 22:16:25

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (513C9424-1E4C-4D44-A50E-7BF5F7EE0869)', Time: '2021-04-08T18:15:23-04:00', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '86224585-1f9b-40a2-a8c7-a754c223c6a5'	System	08 Apr 2021 22:16:25
User entered 'No (N)'	System	08 Apr 2021 22:16:25

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (513C9424-1E4C-4D44-A50E-7BF5F7EE0869)', Time: '2021-04-08T18:15:26-04:00', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '86224585-1f9b-40a2-a8c7-a754c223c6a5' User entered '08 Apr 2021 18:15:26'	System	08 Apr 2021 22:16:25
	System	08 Apr 2021 22:16:25

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '05 Apr 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '09 Apr 2021 23:59'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (513C9424-1E4C-4D44-A50E-7BF5F7EE0869)', Time: '2021-04-12T06:57:49-04:00', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '10ed593e-8eca-46a7-a260-23de94fdb940'	System	12 Apr 2021 10:58:05
User entered 'No (N)'	System	12 Apr 2021 10:58:05

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (513C9424-1E4C-4D44-A50E-7BF5F7EE0869)', Time: '2021-04-12T06:58:00-04:00', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '10ed593e-8eca-46a7-a260-23de94fdb940'	System	12 Apr 2021 10:58:05
User entered 'No (N)'	System	12 Apr 2021 10:58:05

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (513C9424-1E4C-4D44-A50E-7BF5F7EE0869)', Time: '2021-04-12T06:58:03-04:00', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '10ed593e-8eca-46a7-a260-23de94fdb940'	System	12 Apr 2021 10:58:05
User entered '12 Apr 2021 06:58:03'	System	12 Apr 2021 10:58:05

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '12 Apr 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '16 Apr 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (513C9424-1E4C-4D44-A50E-7BF5F7EE0869)', Time: '2021-04-19T15:30:20-04:00', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'd97f2040-9e99-44f0-859c-03e95eaa07ed' User entered 'No (N)'	System	19 Apr 2021 19:30:29
	System	19 Apr 2021 19:30:29



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (513C9424-1E4C-4D44-A50E-7BF5F7EE0869)', Time: '2021-04-19T15:30:23-04:00', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'd97f2040-9e99-44f0-859c-03e95eaa07ed'	System	19 Apr 2021 19:30:29
User entered 'No (N)'	System	19 Apr 2021 19:30:29

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (513C9424-1E4C-4D44-A50E-7BF5F7EE0869)', Time: '2021-04-19T15:30:26-04:00', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'd97f2040-9e99-44f0-859c-03e95eaa07ed' User entered '19 Apr 2021 15:30:26'	System	19 Apr 2021 19:30:29
	System	19 Apr 2021 19:30:29

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '19 Apr 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '23 Apr 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (513C9424-1E4C-4D44-A50E-7BF5F7EE0869)', Time: '2021-04-26T12:39:56-04:00', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'f3ee2b15-91c5-4db7-a2e1-d6f6919d4924'	System	26 Apr 2021 16:40:09
User entered 'No (N)'	System	26 Apr 2021 16:40:09

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (513C9424-1E4C-4D44-A50E-7BF5F7EE0869)', Time: '2021-04-26T12:39:58-04:00', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'f3ee2b15-91c5-4db7-a2e1-d6f6919d4924'	System	26 Apr 2021 16:40:09
User entered 'No (N)'	System	26 Apr 2021 16:40:09

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (513C9424-1E4C-4D44-A50E-7BF5F7EE0869)', Time: '2021-04-26T12:40:00-04:00', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'f3ee2b15-91c5-4db7-a2e1-d6f6919d4924' User entered '26 Apr 2021 12:40:00'	System	26 Apr 2021 16:40:09
	System	26 Apr 2021 16:40:09



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '26 Apr 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '30 Apr 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (513C9424-1E4C-4D44-A50E-7BF5F7EE0869)', Time: '2021-05-03T07:03:26-04:00', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '4722ff07-0e53-4aa3-b7d1-b595cfa0132b'	System	03 May 2021 11:03:40
User entered 'No (N)'	System	03 May 2021 11:03:40

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (513C9424-1E4C-4D44-A50E-7BF5F7EE0869)', Time: '2021-05-03T07:03:30-04:00', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '4722ff07-0e53-4aa3-b7d1-b595cfa0132b'	System	03 May 2021 11:03:40
User entered 'No (N)'	System	03 May 2021 11:03:40

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (513C9424-1E4C-4D44-A50E-7BF5F7EE0869)', Time: '2021-05-03T07:03:35-04:00', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: '4722ff07-0e53-4aa3-b7d1-b595cfa0132b'	System	03 May 2021 11:03:40
User entered '03 May 2021 07:03:35'	System	03 May 2021 11:03:40

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '03 May 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '07 May 2021 23:59'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '10 May 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '14 May 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '17 May 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '21 May 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '24 May 2021 00:01'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '28 May 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '31 May 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '04 Jun 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '07 Jun 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '11 Jun 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '14 Jun 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '18 Jun 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '21 Jun 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '25 Jun 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '28 Jun 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '02 Jul 2021 23:59'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '05 Jul 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '09 Jul 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '12 Jul 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '16 Jul 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '19 Jul 2021 00:01'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '23 Jul 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '26 Jul 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '30 Jul 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '02 Aug 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '06 Aug 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '09 Aug 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '13 Aug 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '16 Aug 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '20 Aug 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '23 Aug 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '27 Aug 2021 23:59'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '30 Aug 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '03 Sep 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '06 Sep 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '10 Sep 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '13 Sep 2021 00:01'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '17 Sep 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '20 Sep 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '24 Sep 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '27 Sep 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '01 Oct 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '04 Oct 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '08 Oct 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '11 Oct 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '15 Oct 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '18 Oct 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '22 Oct 2021 23:59'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '25 Oct 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '29 Oct 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '01 Nov 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '05 Nov 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '08 Nov 2021 00:01'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '12 Nov 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '15 Nov 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '19 Nov 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '22 Nov 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '26 Nov 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '29 Nov 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '03 Dec 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '06 Dec 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '10 Dec 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '13 Dec 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '17 Dec 2021 23:59'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '20 Dec 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '24 Dec 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '27 Dec 2021 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '31 Dec 2021 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '03 Jan 2022 00:01'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '07 Jan 2022 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '10 Jan 2022 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '14 Jan 2022 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '17 Jan 2022 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '21 Jan 2022 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '24 Jan 2022 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '28 Jan 2022 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '31 Jan 2022 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '04 Feb 2022 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '07 Feb 2022 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '11 Feb 2022 23:59'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '14 Feb 2022 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '18 Feb 2022 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '21 Feb 2022 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '25 Feb 2022 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '28 Feb 2022 00:01'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '04 Mar 2022 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '07 Mar 2022 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '11 Mar 2022 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '14 Mar 2022 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '18 Mar 2022 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '21 Mar 2022 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '25 Mar 2022 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '28 Mar 2022 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '01 Apr 2022 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '04 Apr 2022 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '08 Apr 2022 23:59'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '11 Apr 2022 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '15 Apr 2022 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '18 Apr 2022 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '22 Apr 2022 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '25 Apr 2022 00:01'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '29 Apr 2022 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '02 May 2022 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '06 May 2022 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '09 May 2022 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '13 May 2022 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '16 May 2022 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '20 May 2022 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '23 May 2022 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '27 May 2022 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '30 May 2022 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '03 Jun 2022 23:59'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '06 Jun 2022 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '10 Jun 2022 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '13 Jun 2022 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '17 Jun 2022 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '20 Jun 2022 00:01'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '24 Jun 2022 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '27 Jun 2022 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '01 Jul 2022 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '04 Jul 2022 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '08 Jul 2022 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '11 Jul 2022 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '15 Jul 2022 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '18 Jul 2022 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '22 Jul 2022 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '25 Jul 2022 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '29 Jul 2022 23:59'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '01 Aug 2022 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '05 Aug 2022 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '08 Aug 2022 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '12 Aug 2022 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '15 Aug 2022 00:01'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '19 Aug 2022 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '22 Aug 2022 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '26 Aug 2022 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '29 Aug 2022 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '02 Sep 2022 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '05 Sep 2022 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '09 Sep 2022 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '12 Sep 2022 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '16 Sep 2022 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '19 Sep 2022 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '23 Sep 2022 23:59'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '26 Sep 2022 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '30 Sep 2022 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '03 Oct 2022 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '07 Oct 2022 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '10 Oct 2022 00:01'	System	20 Nov 2020 01:11:30



**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '14 Oct 2022 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '17 Oct 2022 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '21 Oct 2022 23:59'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '24 Oct 2022 00:01'	System	20 Nov 2020 01:11:30

**US3432242**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:37:31**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:11:30
Amendment Manager: User entered '28 Oct 2022 23:59'	System	20 Nov 2020 01:11:30

US3432242

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:37:31

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)	26 Apr 2021 10:31:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2021-03-02T13:31:32-05:00', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'ec698a73-9df9-4984-9e86-864a90ac04d2'	System	02 Mar 2021 18:31:43
User entered 'No (N)'	System	02 Mar 2021 18:31:43



**US3432242**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:37:31**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:31:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F4AA601E-73AE-4A5B-9023-5DD78747036A)', Time: '2021-03-02T13:31:38-05:00', User OID: 'PatientReportedOutcome (US3432242)', ODM File OID: 'ec698a73-9df9-4984-9e86-864a90ac04d2'	System	02 Mar 2021 18:31:43
User entered '02 Mar 2021 13:31:38'	System	02 Mar 2021 18:31:43

**US3432242**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:37:31**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 20:42:49

US3432242

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '13 Nov 2020'	(b) (4), (b) (6)	13 Nov 2020 20:42:49

US3432242

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	13 Nov 2020 20:42:49

US3432242

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:31

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 20:42:49

US3432242

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 20:42:53

US3432242

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:14:23
User entered 'I'	System	13 Nov 2020 20:42:53

**US3432242**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:37:31**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Dec 2020 15:48:08



US3432242

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '17 Dec 2020'	(b) (4), (b) (6)	17 Dec 2020 15:48:08

US3432242

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Dec 2020 15:48:08

US3432242

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:31

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	(b) (4), (b) (6)	17 Dec 2020 15:48:08

US3432242

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:23
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Dec 2020 15:48:31

US3432242

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:23
User entered 'I'	System	17 Dec 2020 15:48:31

US3432242

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Jan 2021 16:49:14

US3432242

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '19 Jan 2021'	(b) (4), (b) (6)	19 Jan 2021 16:49:14

US3432242

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	19 Jan 2021 16:49:14



US3432242

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:31

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	(b) (4), (b) (6)	19 Jan 2021 16:49:14

US3432242

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Jan 2021 16:49:21

US3432242

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User entered 'I'	System	19 Jan 2021 16:49:21

US3432242

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:02
User entered 'Yes (Y)'	Tenaizus Woods (b) (4)	19 Feb 2021 16:58:55

US3432242

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:02
User entered '19 Feb 2021'	Tenaizus Woods (b) (4)	19 Feb 2021 16:58:55

US3432242

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:02
User entered 'Contact Made (CONTACT MADE)'	Tenaizus Woods (b) (4)	19 Feb 2021 16:58:55

US3432242

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:37:31

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:02
User entered empty.	Tenaizus Woods (b) (4)	19 Feb 2021 16:58:55

US3432242

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:02
User entered 'Yes (Y)'	Tenaizus Woods (b) (4)	19 Feb 2021 16:58:59



**US3432242**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:37:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User entered 'I'	System	19 Feb 2021 16:58:59

US3432242

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:37:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 13:32:12

US3432242

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:37:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:14
User entered '19 Mar 2021'	(b) (4), (b) (6)	19 Mar 2021 13:32:12

US3432242

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:37:31

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:14
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	19 Mar 2021 13:32:12

**US3432242**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:37:31**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User entered 'VISIT4'	System	19 Mar 2021 13:32:12

US3432242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:14
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	31 Mar 2021 20:14:13

US3432242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:14
User entered '19 Mar 2021'	Bruce Bausk (b) (4)	31 Mar 2021 20:14:13

US3432242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:14
User entered '08:06'	Bruce Bausk (b) (4)	31 Mar 2021 20:14:13



**US3432242**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:37:31**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User entered '19 Mar 2021 08:06'	System	31 Mar 2021 20:14:13

US3432242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:14
User entered '98.1' F	Bruce Bausk (b) (4)	31 Mar 2021 20:14:13

US3432242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:14
User entered 'Oral (Oral)'	Bruce Bausk (b) (4)	31 Mar 2021 20:14:13

US3432242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:14
User entered empty.	Bruce Bausk (b) (4)	31 Mar 2021 20:14:13

US3432242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:14
User entered '51'	Bruce Bausk (b) (4)	31 Mar 2021 20:14:13

US3432242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User entered 'bpm'	System	31 Mar 2021 20:14:13

US3432242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:14
User entered '12'	Bruce Bausk (b) (4)	31 Mar 2021 20:14:13

US3432242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User entered 'breaths/min'	System	31 Mar 2021 20:14:13



US3432242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:14
User entered '162'	Bruce Bausk (b) (4)	31 Mar 2021 20:14:13

US3432242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User entered 'mmHg'	System	31 Mar 2021 20:14:13

US3432242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:14
User entered '83'	Bruce Bausk (b) (4)	31 Mar 2021 20:14:13

US3432242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User entered 'mmHg'	System	31 Mar 2021 20:14:13

US3432242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53

US3432242

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:37:31

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53

US3432242

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:37:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:02
User entered 'No (N)'	(b) (4), (b) (6)	19 Mar 2021 13:32:17

US3432242

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:37:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:02
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 13:32:17



US3432242

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 13:32:40

US3432242

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:02
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 19MAR2021 is recorded under Visit 04 Day 209 visit in EDC, however the same is missing in PPD Central Lab. Please provide sample Accession number and tracking details in query response to confirm with GCL records. Thank you' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 06:48:39
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 19MAR2021 is recorded under Visit 04 Day 209 visit in EDC, however the same is missing in PPD Central Lab. Please provide sample Accession number and tracking details in query response to confirm with GCL records. Thank you' answered with 'PPD reports receiving immuno samples' (Site from DM).	Jun Bai Park Chang (b) (4)	29 Mar 2021 17:01:08
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 19MAR2021 is recorded under Visit 04 Day 209 visit in EDC, however the same is missing in PPD Central Lab. Please provide sample Accession number and tracking details in query response to confirm with GCL records. Thank you' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 04:43:50
User entered '19 Mar 2021'	(b) (4), (b) (6)	19 Mar 2021 13:32:40

US3432242

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:02
User entered '08:20'	(b) (4), (b) (6)	19 Mar 2021 13:32:40

US3432242

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User entered '19 Mar 2021 08:20'	System	19 Mar 2021 13:32:40

US3432242

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:37:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 13:32:52

**US3432242**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:37:31**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:41:53
User entered 'I'	System	19 Mar 2021 13:32:52

US3432242

Folder: Covid-19 Assessment 31 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:37:31

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:28:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	15 Dec 2020 09:40:42
Query 'Data is required. Please complete.' answered with 'made in error. no data needed' (Site from System).	Monica Feeley (b) (4)	10 Nov 2020 21:41:37
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Nov 2020 21:11:35
User entered empty; reason for change Data Entry Error	Xhoi Mitre (b) (4)	02 Nov 2020 21:11:35
User entered '31 Oct 2020'	Xhoi Mitre (b) (4)	02 Nov 2020 20:56:23

US3432242

Folder: Covid-19 Assessment 31 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:37:31

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:28:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	15 Dec 2020 09:40:44
Query 'Data is required. Please complete.' answered with 'made in error. no data needed' (Site from System).	Monica Feeley (b) (4)	10 Nov 2020 21:41:40
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Nov 2020 21:11:35
User entered empty; reason for change Data Entry Error	Xhoi Mitre (b) (4)	02 Nov 2020 21:11:35
User entered '10:05'	Xhoi Mitre (b) (4)	02 Nov 2020 20:56:23



US3432242

Folder: Covid-19 Assessment 31 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:37:31

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:28:43
User entered empty.	System	02 Nov 2020 21:11:35
User entered '31 Oct 2020 10:05'	System	02 Nov 2020 20:56:23

US3432242

Folder: Covid-19 Assessment 31 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:37:31

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:28:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	15 Dec 2020 09:40:46
Query 'Data is required. Please complete.' answered with 'made in error. no data needed' (Site from System).	Monica Feeley (b) (4)	10 Nov 2020 21:41:41
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Nov 2020 21:11:35
User entered empty; reason for change Data Entry Error	Xhoi Mitre (b) (4)	02 Nov 2020 21:11:35
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Xhoi Mitre (b) (4)	02 Nov 2020 20:56:23

US3432242

Folder: Covid-19 Assessment 31 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:37:31

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:28:43
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	15 Dec 2020 09:40:47
Query 'Data is required. Please complete.' answered with 'made in error. no data needed' (Site from System).	Monica Feeley (b) (4)	10 Nov 2020 21:41:44
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Nov 2020 21:11:35
User entered empty; reason for change Data Entry Error	Xhoi Mitre (b) (4)	02 Nov 2020 21:11:35
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	02 Nov 2020 20:56:23

US3432242

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:37:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	Tenaizus Woods (b) (4)	08 Jan 2021 14:49:51

US3432242

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:37:31

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '08 Jan 2021'	Tenaizus Woods (b) (4)	08 Jan 2021 14:49:51

US3432242

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:37:31

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Clinic (Clinic)'	Tenaizus Woods (b) (4)	08 Jan 2021 14:49:51

**US3432242**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:37:31**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:15
User entered 'UNBLND_DECIDE'	System	08 Jan 2021 14:49:51

US3432242

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:37:31

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '6 Jan 2021'	Tenaizus Woods (b) (4)	08 Jan 2021 14:50:42



**US3432242**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:37:31**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:15
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:13
User entered '0'	(b) (4), (b) (6)	09 Apr 2021 12:37:04
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:24:12

US3432242

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:37:31

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	Tenaizus Woods (b) (4)	08 Jan 2021 14:50:42

US3432242

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:37:31

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:15
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:13
User closed query 'Per Sponsor Review, per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	11 Apr 2021 06:59:42
Query 'Per Sponsor Review, per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 12:37:08
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6)	09 Apr 2021 12:37:04
User opened query 'Per Sponsor Review, per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 05:05:02
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:24:12

US3432242

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:37:31

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '08 Jan 2021'	Tenaizus Woods (b) (4)	08 Jan 2021 14:50:42

US3432242

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:37:31

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'mRNA-1273 (mRNA-1273)'	Tenaizus Woods (b) (4)	08 Jan 2021 14:50:42

US3432242

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:37:31

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 03:04:41
User entered 'mRNA-1273 (mRNA-1273)'	Tenaizus Woods (b) (4)	08 Jan 2021 14:50:42

US3432242

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:37:31

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 03:04:41
User entered 'mRNA-1273 (mRNA-1273)'	Tenaizus Woods (b) (4)	08 Jan 2021 14:50:42

US3432242

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:37:31

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'No (N)'	Tenaizus Woods (b) (4)	08 Jan 2021 14:50:42



**US3432242**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:37:31**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:15
User entered empty.	System	08 Jan 2021 14:50:42

**US3432242**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:37:31**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:15
User entered empty.	System	08 Jan 2021 14:50:42

US3432242

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	Tenaizus Woods (b) (4)	08 Jan 2021 15:10:00

US3432242

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:31

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '08 Jan 2021'	Tenaizus Woods (b) (4)	08 Jan 2021 15:10:00

US3432242

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:37:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User closed query 'Data is required. Please provide.' (Site from System).	System	08 Jan 2021 15:58:00
User entered '08:16' reason for change: Data Entry Error	Tenaizus Woods (b) (4)	08 Jan 2021 15:58:00
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Jan 2021 15:10:00
User entered empty.	Tenaizus Woods (b) (4)	08 Jan 2021 15:10:00

**US3432242**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:37:31**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:15
User entered '08 Jan 2021 08:16'	System	08 Jan 2021 15:58:00
User entered empty.	System	08 Jan 2021 15:10:00

US3432242

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:37:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	Tenaizus Woods (b) (4)	08 Jan 2021 15:10:11

US3432242

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:37:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '08 Jan 2021'	Tenaizus Woods (b) (4)	08 Jan 2021 15:10:11



US3432242

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:37:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '08:21' reason for change: Data Entry Error	Tenaizus Woods (b) (4)	08 Jan 2021 15:58:08
User entered empty.	Tenaizus Woods (b) (4)	08 Jan 2021 15:10:11

**US3432242**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:37:31**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:44:15
User entered '08 Jan 2021 08:21'	System	08 Jan 2021 15:58:08
User entered empty.	System	08 Jan 2021 15:10:11

US3432242

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:37:31

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:53:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:00:59
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	17 Oct 2020 20:43:41

US3432242

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:31

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:01:09
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:16:07
User entered	System	19 Oct 2020 16:15:55
'USA-US078-2020-mRNA-1273-P301000006'		
User entered 'New'	(b) (4), (b) (6)	19 Oct 2020 16:15:55

US3432242

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:31

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Lymphomas non-Hodgkin's B-cell, HLT: Splenic marginal zone lymphomas, PT: Splenic marginal zone lymphoma, LLT: Splenic marginal zone lymphoma - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 13:29:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Feb 2021 13:29:59
Data point term sent to Coder	System	10 Feb 2021 20:02:45
DataPoint Un-verified.	Monica Feeley (b) (4)	10 Feb 2021 20:02:36
	(b) (4)	
Coding entries removed.	Monica Feeley (b) (4)	10 Feb 2021 20:02:36
	(b) (4)	
User entered 'Marginal zone splenic B-cell lymphoma' reason for change: New Information	Monica Feeley (b) (4)	10 Feb 2021 20:02:36
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:02:01
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Leukaemias, HLT: Leukaemias chronic lymphocytic, PT: Chronic lymphocytic leukaemia, LLT: Chronic lymphocytic leukemia - version MedDRA\\23.0.	Coder Import (b) (4)	18 Oct 2020 02:25:29
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Oct 2020 02:25:29
Data point term sent to Coder	System	17 Oct 2020 20:49:08
User entered 'CLL - Chronic lymphocytic leukemia' reason for change: Data Entry Error	Xhoi Mitre (b) (4)	17 Oct 2020 20:48:11
	(b) (4)	
Data point term sent to Coder	System	17 Oct 2020 20:48:07
User entered 'CLL'	Xhoi Mitre (b) (4)	17 Oct 2020 20:47:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:02:04
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	17 Oct 2020 20:47:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:02:06
User entered 'No (N)'	Xhoi Mitre (b) (4)	17 Oct 2020 20:47:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:02:08
User entered 'No (N)'	Xhoi Mitre (b) (4)	17 Oct 2020 20:47:26
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:02:13
User entered '8 Oct 2020'	Xhoi Mitre (b) (4)	17 Oct 2020 20:47:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:31

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:02:15
User entered empty.	Xhoi Mitre (b) (4)	17 Oct 2020 20:47:26
	(b) (4)	

**US3432242**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:37:31**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Oct 2020 20:47:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:02:18
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	17 Oct 2020 20:47:26
	(b) (4)	

US3432242

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
	(b) (4), (b) (6)	02 Nov 2020 13:55:18
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	Monica Feeley (b) (4)	30 Oct 2020 13:13:58
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'unlikely to resolve' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 19:18:01
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 15:02:20
DataPoint Verified.	Xhoi Mitre (b) (4)	17 Oct 2020 20:47:26
User entered empty.	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:31

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:02:22
User entered empty.	Xhoi Mitre (b) (4)	17 Oct 2020 20:47:26
	(b) (4)	

**US3432242**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:37:31**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Oct 2020 20:47:26

US3432242

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:31

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:02:23
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Xhoi Mitre (b) (4)	17 Oct 2020 20:47:26
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:02:26
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	17 Oct 2020 20:47:26
	(b) (4)	

US3432242

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:31

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:02:27
User entered '0'	Xhoi Mitre (b) (4)	17 Oct 2020 20:47:26
	(b) (4)	

US3432242

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:02:29
User entered '0'	Xhoi Mitre (b) (4)	17 Oct 2020 20:47:26
	(b) (4)	

US3432242

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:02:31
User entered '0'	Xhoi Mitre (b) (4)	17 Oct 2020 20:47:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:02:32
User entered empty.	Xhoi Mitre (b) (4)	17 Oct 2020 20:47:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:31

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:02:34
User entered empty.	Xhoi Mitre (b) (4)	17 Oct 2020 20:47:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:02:36
User entered empty.	Xhoi Mitre (b) (4)	17 Oct 2020 20:47:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:02:38
User entered empty.	Xhoi Mitre (b) (4)	17 Oct 2020 20:47:26
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:02:39
User entered '0'	Xhoi Mitre (b) (4)	17 Oct 2020 20:47:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:02:41
User entered '0'	Xhoi Mitre (b) (4)	17 Oct 2020 20:47:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:02:42
User entered 'I'	Xhoi Mitre (b) (4)	17 Oct 2020 20:47:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:02:44
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4)	17 Oct 2020 20:47:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:02:47
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4)	17 Oct 2020 20:47:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:02:48
User entered 'Not Applicable (NOT APPLICABLE)'	Xhoi Mitre (b) (4)	17 Oct 2020 20:48:46
reason for change: Data Entry Error	(b) (4)	
User entered 'None (NONE)'	Xhoi Mitre (b) (4)	17 Oct 2020 20:47:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:31

None

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User closed query 'Per DM CLR: Please review if treatments were given for this Serious AE as treatments are expected. If treatments were given, please update to record accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 04:23:02
Query 'Per DM CLR: Please review if treatments were given for this Serious AE as treatments are expected. If treatments were given, please update to record accordingly. Otherwise, clarify.' answered with 'treatments were not given yet. We will update if treatments are given' (Site from DM).	Monica Feeley (b) (4)	30 Oct 2020 13:16:52
	(b) (4)	
User opened query 'Per DM CLR: Please review if treatments were given for this Serious AE as treatments are expected. If treatments were given, please update to record accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 23:04:54
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:02:51
User entered 'I'	Xhoi Mitre (b) (4)	17 Oct 2020 20:47:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:02:53
User entered '0'	Xhoi Mitre (b) (4)	17 Oct 2020 20:47:26
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:02:55
User entered '0'	Xhoi Mitre (b) (4)	17 Oct 2020 20:47:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:31

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
	(b) (4), (b) (6)	02 Nov 2020 13:55:24
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	Monica Feeley (b) (4)	30 Oct 2020 13:15:11
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Not likely to resolve' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 19:18:32
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 15:02:57
DataPoint Verified.	Xhoi Mitre (b) (4)	17 Oct 2020 20:47:26
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:31

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:02:59
User entered empty.	Xhoi Mitre (b) (4)	17 Oct 2020 20:47:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:31

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative = ADDITIONAL FLOW CYTOMETRY RAN 06NOV2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 07:45:23
User closed query 'Per DM CLR: Narrative = BLOOD COUNT REPEATED ON 08OCT2020 WITH FLOW CYTOMETRY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 07:45:21
User closed query 'Per DM CLR: Narrative = ROUTINE CBC DONE ON SEPT 28TH. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 07:45:15
Query 'Per DM CLR: Narrative = ADDITIONAL FLOW CYTOMETRY RAN 06NOV2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 13:30:57
Query 'Per DM CLR: Narrative = BLOOD COUNT REPEATED ON 08OCT2020 WITH FLOW CYTOMETRY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 13:30:53
Query 'Per DM CLR: Narrative = ROUTINE CBC DONE ON SEPT 28TH. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 13:30:49
User opened query 'Per DM CLR: Narrative = ADDITIONAL FLOW CYTOMETRY RAN 06NOV2020. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 09:21:35

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = BLOOD COUNT REPEATED ON 08OCT2020 WITH FLOW CYTOMETRY. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 09:21:29
User opened query 'Per DM CLR: Narrative = ROUTINE CBC DONE ON SEPT 28TH. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 09:21:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User closed query 'PV Query: Please provide results of flow cytometry. Please leave query open until obtained.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 15:10:19

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'ROUTINE CBC DONE ON SEPT 28TH IN PREPARATION FOR REGULAR PCP APPOINTMENT SHOWED LYMPHOCYTOSIS. BLOOD COUNT REPEATED ON 08OCT2020 WITH FLOW CYTOMETRY CONFIRMING CLL. HAS A PLANNED APPOINTMENT ON 11/11 WITH HEMATOLOGIST. Additional flow cytometry ran 06NOV2020. 30OCT2020: WBC: 28SEP2020 17.6 X 10*3 / UL; 08OCT2020 21.3 X 10*3 / UL  08OCT2020: FLOW CYTOMETRY RESULTS: Immunophenotypic findings in keeping with involvement by a CD5 negative/CD10 negative B-cell non-Hodgkin lymphoma. This immunophenotype is non-specific. Approximately 86% of total acquired events are evaluable non-debris events.   The viability of the analyzed non-debris events done by 7-AAD is 95%. CD45-bright, low side-scatter gated lymphocytes comprise 81% of total analyzed events. B cells comprise 76% of lymphoid-gated events and demonstrate monoclonal kappa light chain restriction (bright kappa expression seen). They co-express pan-B cell markers CD19, CD20 and CD22 along with CD11c (subset dim). They do not express any other characteristic antigens including CD5, CD10, CD23, CD25, CD34, CD38 and CD103. T cells comprise 24% of lymphoid gated events and express mature lineage antigens (CD3, CD5, CD2 and CD7). A subset of T cells shows dim/variable loss of CD7 (favor non-specific finding). T cells have a CD4:CD8 ratio of 0.9. CD56 positive, CD3 negative natural killer cells represent 3% of gated lymphocytes.  06NOV2020: FLOW CYTOMETRY RESULTS:  ABERRANT POPULATION OF B CELLS (72% OF GATED EVENTS; 53% OF TOTAL EVENTS) POSITIVE FOR B-LYMPHOID MARKERS CD19, CD20, CO-EXPRESSES CD11C, EXHIBITS  BRIGHT MONOTYPIC STAINING FOR SURFACE IMMUNOGLOBULIN KAPPA, AND NEGATIVE FOR CD10, CD5, CD23, CD38, CD25, CD103, AND OTHER T-CELL	Monica Feeley (b) (4) (b) (4)	10 Feb 2021 20:12:54

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
MARKERS, CONSISTENT WITH INVOLVEMENT BY A B-CELL LYMPHOPROLIFERATIVE DISORDER.    BASED ON RESULTS, DIAGNOSIS WAS UPDATED. PT IS ASYMPTOMATIC CURRENTLY. NO TREATMENT STARTED.'		
reason for change: New Information Query 'PV Query: Please provide results of flow cytometry. Please leave query open until obtained.' answered with 'updated with results' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	10 Feb 2021 20:05:56
DataPoint Un-verified.	Monica Feeley (b) (4) (b) (4)	10 Feb 2021 20:05:44

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Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:31

[Narrative](#)

Audit	User	Time (GMT)
User entered 'ROUTINE CBC DONE ON SEPT 28TH IN PREPARATION FOR REGULAR PCP APPOINTMENT SHOWED LYMPHOCYTOSIS. BLOOD COUNT REPEATED ON 08OCT2020 WITH FLOW CYTOMETRY CONFIRMING CLL. HAS A PLANNED APPOINTMENT ON 11/11 WITH HEMATOLOGIST. 30OCT2020: WBC: 28SEP2020 17.6 X 10*3 / UL; 08OCT2020 21.3 X 10*3 / UL  08OCT2020 Flow cytometry results:  aberrant population of B cells (72% of gated events; 53% of total events) positive for B-lymphoid markers CD19, CD20, co-expresses CD11c, exhibits  bright monotypic staining for surface immunoglobulin kappa, and negative for CD10, CD5, CD23, CD38, CD25, CD103, and other T-cell markers, consistent with involvement by a B-cell lymphoproliferative disorder.   Also within the lymphocyte gate, 22% of gated events (15% of total events) are CD3-positive T cells expressing mature T-cell markers (CD2, CD5 and CD7) with a  CD4:CD8 ratio of 1.2. Within the T-cell population is a subset of T cells (3% of gated events; 2% of total events) that are positive for CD3, CD2, CD7, CD5(dim), CD8, CD57, consistent with T-cell large granular lymphocytes. NK cells (positive for CD8(dim, subset), CD7, CD2, CD16, and CD56) comprise 5% of gated events (4% of total events).   Based on results, diagnosis was updated. Pt is asymptomatic currently. no treatment started.' reason for change: New Information	Monica Feeley (b) (4) (b) (4)	10 Feb 2021 20:05:44
User closed query 'PV Query: Please report if the patient had any family history or personal risk factors for chronic lymphocytic leukemia. Please leave query open until obtained. ' (Site from Safety).	(b) (4), (b) (6)	11 Jan 2021 12:51:28
Query 'PV Query: Please report if the patient had any family history or personal risk factors for chronic lymphocytic leukemia. Please leave query open until obtained. ' answered with 'Patient reports no family history or personal risk factors for CLL.' (Site from Safety).	Tenaizus Woods (b) (4) (b) (4)	08 Jan 2021 15:11:57



US3432242

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:31

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide results of flow cytometry. Please leave query open until obtained.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 18:19:33
User opened query 'PV Query: Please report if the patient had any family history or personal risk factors for chronic lymphocytic leukemia. Please leave query open until obtained. ' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 18:19:11
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 03:41:42
User closed query 'PV Query: Please report if the patient had any family history or personal risk factors for chronic lymphocytic leukemia.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 13:55:36
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 13:55:33
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 13:55:30
DataPoint Un-verified.	Monica Feeley (b) (4)	30 Oct 2020 13:36:59
User entered 'ROUTINE CBC DONE ON SEPT 28TH IN PREPARATION FOR REGULAR PCP APPOINTMENT SHOWED LYMPHOCYTOSIS. BLOOD COUNT REPEATED ON 08OCT2020 WITH FLOW CYTOMETRY CONFIRMING CLL. HAS A PLANNED APPOINTMENT ON 11/11 WITH HEMATOLOGIST. 30OCT2020: WBC: 28SEP2020 17.6 x 10*3 / uL; 08OCT2020 21.3 x 10*3 / uL Waiting for participant to send flow cytometry results' reason for change: Data Entry Error	Monica Feeley (b) (4)	30 Oct 2020 13:36:59

US3432242

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:31

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'WBC: 28SEP2020 17.6 x 10*3 / uL; 08OCT2020 21.3 x 10*3 / uL Waiting for participant to send flow cytometry results. Participants next appointment is in November 2020' (Site from Safety).	Monica Feeley (b) (4)	30 Oct 2020 13:36:35
Query 'PV Query: Please report if the patient had any family history or personal risk factors for chronic lymphocytic leukemia.' answered with 'we will follow up with participant at next study visit to determine if there were any risk factors' (Site from Safety).	Monica Feeley (b) (4)	30 Oct 2020 13:17:14
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'No treatment provided thus far. Will update if treatment is given.' (Site from Safety).	Monica Feeley (b) (4)	30 Oct 2020 13:16:17
User opened query 'PV Query: Please report if the patient had any family history or personal risk factors for chronic lymphocytic leukemia.' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 19:18:56
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 19:18:44
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 19:18:18
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:01

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3432242

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:37:31

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Routine CBC done on sept 28th in preparation for regular PCP appointment showed lymphocytosis. Blood count repeated on 08Oct2020 with flow cytometry confirming CLL. Has a planned appointment on 11/11 with hematologist.'	Xhoi Mitre (b) (4)	17 Oct 2020 20:47:26

**US3432242**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:37:31**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Oct 2020 20:47:26

**US3432242**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:37:31**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Oct 2020 20:47:26

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:37:31

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:53:52
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:02
User closed query 'Per DM CLR: Per Diary Dose 2 Day 1, Headache (General) = 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)	11 Mar 2021 07:07:11
Query 'Per DM CLR: Per Diary Dose 2 Day 1, Headache (General) = 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 'Participant took tylenol on 21Sep2021. Already listed on con meds. Added indication of headache' (Site from DM).	Bruce Bausk (b) (4)	10 Mar 2021 17:28:26
User opened query 'Per DM CLR: Per Diary Dose 2 Day 1, Headache (General) = 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)	18 Feb 2021 02:56:32
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 03:40:04
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:05:32

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 16:08:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 16:08:16
Data point term sent to Coder	System	22 Aug 2020 16:06:58
User entered 'atorvastatin'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:06:53

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'No (N)'	Phoebe Cunningham	22 Aug 2020 16:06:53
	(b) (4)	



US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'hypercholesterolemia'	Phoebe Cunningham	22 Aug 2020 16:06:53
	(b) (4)	

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '10'	Phoebe Cunningham	22 Aug 2020 16:06:53
	(b) (4)	

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'mg (mg)'	Phoebe Cunningham	22 Aug 2020 16:06:53
	(b) (4)	

US3432242

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:37:31**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	Phoebe Cunningham	22 Aug 2020 16:06:53
	(b) (4)	

US3432242

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:37:31**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'once daily (QD)'	Phoebe Cunningham	22 Aug 2020 16:06:53
	(b) (4)	

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:31

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	Phoebe Cunningham	22 Aug 2020 16:06:53
	(b) (4)	

US3432242

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:37:31**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Oral (ORAL)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:06:53

US3432242

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:37:31**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	Phoebe Cunningham	22 Aug 2020 16:06:53
	(b) (4)	



US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:31

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'un UNK 2014'	Phoebe Cunningham	22 Aug 2020 16:06:53
	(b) (4)	

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:31

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '0'	Phoebe Cunningham	22 Aug 2020 16:06:53
	(b) (4)	

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	Phoebe Cunningham	22 Aug 2020 16:06:53
	(b) (4)	

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:37:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	Phoebe Cunningham	22 Aug 2020 16:06:53
	(b) (4)	

US3432242

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:37:31**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'No (N)'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:06:53

**US3432242**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:37:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 16:06:53

**US3432242**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:37:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 16:06:53

**US3432242**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:37:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Aug 2020 16:06:53



US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:31

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: FLUOXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 16:09:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 16:09:17
Data point term sent to Coder	System	22 Aug 2020 16:08:02
User entered 'Fluoxetine'	Phoebe Cunningham	22 Aug 2020 16:07:48
	(b) (4)	

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'No (N)'	Phoebe Cunningham	22 Aug 2020 16:07:48
	(b) (4)	

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Anxiety'	Phoebe Cunningham	22 Aug 2020 16:07:48
	(b) (4)	

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '10'	Phoebe Cunningham	22 Aug 2020 16:07:48
	(b) (4)	

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'mg (mg)'	Phoebe Cunningham	22 Aug 2020 16:07:48
	(b) (4)	

US3432242

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:37:31**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 02:08:53
User entered empty.	Phoebe Cunningham (b) (4) [REDACTED]	22 Aug 2020 16:07:48

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'once daily (QD)'	Phoebe Cunningham	22 Aug 2020 16:07:48
	(b) (4)	

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 02:08:53
User entered empty.	Phoebe Cunningham (b) (4) [REDACTED]	22 Aug 2020 16:07:48



US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Oral (ORAL)'	Phoebe Cunningham	22 Aug 2020 16:07:48
	(b) (4)	

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	Phoebe Cunningham	22 Aug 2020 16:07:48
	(b) (4)	

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:31

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'un UNK 2001'	Phoebe Cunningham (b) (4)	22 Aug 2020 16:07:48

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:31

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '0'	Phoebe Cunningham	22 Aug 2020 16:07:48
	(b) (4)	

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	Phoebe Cunningham	22 Aug 2020 16:07:48
	(b) (4)	

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:37:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 02:08:53
User entered empty.	Phoebe Cunningham (b) (4) [REDACTED]	22 Aug 2020 16:07:48

US3432242

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:37:31**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'No (N)'	Phoebe Cunningham	22 Aug 2020 16:07:48
	(b) (4)	

**US3432242**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:37:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 16:07:48



US3432242

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:37:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Aug 2020 16:07:48

**US3432242**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:37:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Aug 2020 16:07:48

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN, PRODUCTSYNONYM: MELATONINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 16:10:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 16:10:17
Data point term sent to Coder	System	22 Aug 2020 16:09:03
User entered 'Melatonine'	Phoebe Cunningham	22 Aug 2020 16:08:29
	(b) (4)	

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'No (N)'	Phoebe Cunningham	22 Aug 2020 16:08:29
	(b) (4)	

US3432242

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:37:31**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Insomnia'	Phoebe Cunningham	22 Aug 2020 16:08:29
	(b) (4)	

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '3'	Phoebe Cunningham	22 Aug 2020 16:08:29
	(b) (4)	

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'mg (mg)'	Phoebe Cunningham	22 Aug 2020 16:08:29
	(b) (4)	

US3432242

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:37:31**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	Phoebe Cunningham	22 Aug 2020 16:08:29
	(b) (4)	



US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'as needed (PRN)'	Phoebe Cunningham	22 Aug 2020 16:08:29
	(b) (4)	

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 02:08:53
User entered empty.	Phoebe Cunningham (b) (4) [REDACTED]	22 Aug 2020 16:08:29

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Oral (ORAL)'	Phoebe Cunningham	22 Aug 2020 16:08:29
	(b) (4)	

US3432242

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:37:31**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	Phoebe Cunningham	22 Aug 2020 16:08:29
	(b) (4)	

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:31

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'un Jul 2020'	Phoebe Cunningham	22 Aug 2020 16:08:29
	(b) (4)	

US3432242

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:37:31**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '0'	Phoebe Cunningham	22 Aug 2020 16:08:29
	(b) (4)	

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	Phoebe Cunningham	22 Aug 2020 16:08:29
	(b) (4)	

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:37:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	Phoebe Cunningham	22 Aug 2020 16:08:29
	(b) (4)	



US3432242

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:37:31**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'No (N)'	Phoebe Cunningham	22 Aug 2020 16:08:29
	(b) (4)	

**US3432242**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:37:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Aug 2020 16:08:29

**US3432242**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:37:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Aug 2020 16:08:29

**US3432242**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:37:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Aug 2020 16:08:29

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:50
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) (b) (4)	10 Mar 2021 17:29:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Mar 2021 17:29:54
Data point term sent to Coder Coding entries removed.	System Bruce Bausk (b) (4) (b) (4)	10 Mar 2021 17:29:12 10 Mar 2021 17:28:50
User signature succeeded.	Lindsey Baden (b) (4) (b) (4)	19 Feb 2021 02:08:53
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) (b) (4)	07 Oct 2020 15:15:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 15:15:56
Data point term sent to Coder User entered 'Tylenol'	System Kathleen Garvey (b) (4) (b) (4)	07 Oct 2020 14:23:30 07 Oct 2020 14:22:46

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'No (N)'	Kathleen Garvey (b) (4)	07 Oct 2020 14:22:46

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:50
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:13
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 FEVER, 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 FEVER, HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 11:40:34
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the FEVER, 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 FEVER, HEADACHE did not meet the AE reporting criteria. ' answered with 'no AE needed. this is during the diary time frame. please see' (Site from DM).	Monica Feeley (b) (4)	07 Apr 2021 21:48:59

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:31

[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 FEVER, 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 FEVER, HEADACHE did not meet the AE reporting criteria. ' (Site from DM). Signature has been broken.	(b) (4), (b) (6) (b) (4)	30 Mar 2021 06:35:20
	Bruce Bausk (b) (4) (b) (4)	10 Mar 2021 17:28:50
User entered 'FEVER, headache' reason for change: Data Entry Error	Bruce Bausk (b) (4) (b) (4)	10 Mar 2021 17:28:50
User signature succeeded.	Lindsey Baden (b) (4) (b) (4)	19 Feb 2021 02:08:53
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 FEVER 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 FEVER did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6) (b) (4)	23 Nov 2020 07:50:16



US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:31

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the FEVER 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 FEVER did not meet the AE reporting criteria.' answered with 'This medication was taken for fever reported in the eduary, not meeting the criteria for AE reporting' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 16:30:25
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 FEVER 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 FEVER did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 18:47:44
User entered 'Fever'	Kathleen Garvey (b) (4) (b) (4)	07 Oct 2020 14:22:46

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 07:50:26
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'Pt has been contacted and dosage has been updated' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 20:49:08
User entered '500' reason for change: Per Query Resolution	(b) (4), (b) (6)	13 Nov 2020 20:48:55
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 18:48:04
User entered '200'	Kathleen Garvey (b) (4)	07 Oct 2020 14:22:46

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'mg (mg)'	Kathleen Garvey (b) (4)	07 Oct 2020 14:22:46

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	Kathleen Garvey (b) (4)	07 Oct 2020 14:22:46

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'once (ONCE)'	Kathleen Garvey (b) (4)	07 Oct 2020 14:22:46

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	Kathleen Garvey (b) (4)	07 Oct 2020 14:22:46

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Oral (ORAL)'	Kathleen Garvey (b) (4)	07 Oct 2020 14:22:46

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	Kathleen Garvey (b) (4)	07 Oct 2020 14:22:46



US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '21 Sep 2020'	Kathleen Garvey (b) (4)	07 Oct 2020 14:22:46

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '0'	Kathleen Garvey (b) (4)	07 Oct 2020 14:22:46

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:31

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'No (N)'	Kathleen Garvey (b) (4)	07 Oct 2020 14:22:46

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '21 Sep 2020'	Kathleen Garvey (b) (4)	07 Oct 2020 14:22:46

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:37:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:50
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	07 Oct 2020 14:22:46

**US3432242**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:37:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:50
User entered empty.	System	07 Oct 2020 14:22:46

US3432242

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:37:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:50
User entered empty.	System	07 Oct 2020 14:22:46

US3432242

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:37:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:50
User entered empty.	System	07 Oct 2020 14:22:46



US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 15:05:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Oct 2020 15:05:37
Data point term sent to Coder	System	13 Oct 2020 15:04:59
User entered 'Influenza Vaccine'	(b) (4), (b) (6)	13 Oct 2020 15:04:01

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 15:04:01

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Influenza prophylaxis'	(b) (4), (b) (6)	13 Oct 2020 15:04:01

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'I'	(b) (4), (b) (6)	13 Oct 2020 15:04:01

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Other (OTHER)'	(b) (4), (b) (6)	13 Oct 2020 15:04:01

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Vaccination'	(b) (4), (b) (6)	13 Oct 2020 15:04:01

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'once (ONCE)'	(b) (4), (b) (6)	13 Oct 2020 15:04:01

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:31

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 15:04:01



US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	13 Oct 2020 15:04:01

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 15:04:01

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '8 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 15:04:01

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 15:04:01

**US3432242**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:37:31**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 15:04:01

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	13 Oct 2020 15:04:10
User entered '08 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 15:04:10
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	13 Oct 2020 15:04:01
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 15:04:01

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:37:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 15:04:01

US3432242

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:37:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:45
User entered empty.	System	13 Oct 2020 15:04:01



US3432242

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:37:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:45
User entered empty.	System	13 Oct 2020 15:04:01

US3432242

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:37:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:45
User entered empty.	System	13 Oct 2020 15:04:01

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:31

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE RGE (CHO), PRODUCTSYNONYM: SHINGRIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 05:13:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 05:13:43
Data point term sent to Coder	System	13 Nov 2020 20:51:27
User entered 'shingrix vaccination'	(b) (4), (b) (6)	13 Nov 2020 20:50:58

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:31

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 20:50:58

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'prophylaxis'	(b) (4), (b) (6)	13 Nov 2020 20:50:58

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:31

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'I'	(b) (4), (b) (6)	13 Nov 2020 20:50:58

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:31

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Other (OTHER)'	(b) (4), (b) (6)	13 Nov 2020 20:50:58

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:31

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'injection'	(b) (4), (b) (6)	13 Nov 2020 20:50:58



US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:31

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'once (ONCE)'	(b) (4), (b) (6)	13 Nov 2020 20:50:58

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 20:50:58

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:31

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	13 Nov 2020 20:50:58

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:31

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 20:50:58

**US3432242**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:37:31**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '8 Nov 2020'	(b) (4), (b) (6)	13 Nov 2020 20:50:58

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '0'	(b) (4), (b) (6)	13 Nov 2020 20:50:58

**US3432242**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:37:31**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 20:50:58

US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '8 Nov 2020'	(b) (4), (b) (6)	13 Nov 2020 20:50:58



US3432242

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:37:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'No (N)'	(b) (4), (b) (6)	13 Nov 2020 20:50:58

**US3432242**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:37:31**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:40
User entered empty.	System	13 Nov 2020 20:50:58

**US3432242**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:37:31**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:40
User entered empty.	System	13 Nov 2020 20:50:58

**US3432242**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:37:31**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:42:40
User entered empty.	System	13 Nov 2020 20:50:58

US3432242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:37:31

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:53:52
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:43:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Mar 2021 13:27:28

US3432242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:37:31

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:09:13
User entered '28 Sep 2020'	(b) (4), (b) (6) [REDACTED]	19 Mar 2021 13:28:04

US3432242

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 17:37:31**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:09:13
User entered 'Routine CBC'	(b) (4), (b) (6) [REDACTED]	19 Mar 2021 13:28:04

US3432242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:37:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:13
User closed query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 11:39:52
Query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' answered with 'updated' (Site from DM).	Monica Feeley (b) (4)	06 Apr 2021 17:26:18
User entered 'Other (OTHER)' reason for change: Data Entry Error	Monica Feeley (b) (4)	06 Apr 2021 17:26:12
User opened query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 10:48:28
User entered 'Medical History (MH)'	(b) (4), (b) (6)	19 Mar 2021 13:28:04



US3432242

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 17:37:31**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:13
User entered 'General Health' reason for change: Data Entry Error	Monica Feeley (b) (4)	06 Apr 2021 17:26:12
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 13:28:04

US3432242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:37:31

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:25
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:13
User entered '08 Oct 2020'	(b) (4), (b) (6)	19 Mar 2021 13:29:01

US3432242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:37:31

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:25
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:13
User entered 'Blood count repeat'	(b) (4), (b) (6)	19 Mar 2021 13:29:01

US3432242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:37:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:25
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:13
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4), (b) (6)	19 Mar 2021 13:29:01

US3432242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:37:31

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:25
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:13
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 13:29:01

US3432242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:37:31

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:28
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:13
User entered '06 Nov 2020'	(b) (4), (b) (6)	19 Mar 2021 13:29:29

US3432242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:37:31

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:28
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:13
User entered 'fLOW CYTOMETRY'	(b) (4), (b) (6)	19 Mar 2021 13:29:29

US3432242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:37:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:28
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:13
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4), (b) (6)	19 Mar 2021 13:29:29



US3432242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:37:31

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:28
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:13
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 13:29:29

US3432242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:37:31

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:32
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:13
User entered '31 Dec 2020'	(b) (4), (b) (6)	19 Mar 2021 13:29:53

US3432242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:37:31

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:32
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:13
User entered 'ct sCAN (NECK TO PELVIS)'	(b) (4), (b) (6)	19 Mar 2021 13:29:53

US3432242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:37:31

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:32
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:13
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4), (b) (6)	19 Mar 2021 13:29:53

US3432242

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:37:31

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:13:32
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:09:13
User entered empty.	(b) (4), (b) (6)	19 Mar 2021 13:29:53

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:11
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered	System	19 Oct 2020 16:15:55
'USA-US078-2020-MRNA-1273-P301000006'		

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:13
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'Yes (Y)'	System	19 Oct 2020 16:15:55

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

Death

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:15
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'No (N)'	System	19 Oct 2020 16:15:55



US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:17
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'No (N)'	System	19 Oct 2020 16:15:55

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:18
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'No (N)'	System	19 Oct 2020 16:15:55

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:21
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'No (N)'	System	19 Oct 2020 16:15:55

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'No (N)'	System	19 Oct 2020 16:15:55

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:26
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'Yes (Y)'	System	19 Oct 2020 16:15:55

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:28
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'Lindsey'	System	19 Oct 2020 16:15:55

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'Baden'	System	19 Oct 2020 16:15:55

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'MA'	System	19 Oct 2020 16:15:55



US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 13:55:54
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:04:00
User entered 'US'	System	19 Oct 2020 16:21:23

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '3'	System	11 Feb 2021 15:11:17
User entered '2'	System	02 Nov 2020 13:56:05
User entered '1'	System	19 Oct 2020 16:21:23

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:11
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'USA-US078-2020-MRNA-1273-P301000006'	System	19 Oct 2020 16:15:55

**US3432242**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:37:31**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:13
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'Yes (Y)'	System	19 Oct 2020 16:15:55

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

Death

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:15
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'No (N)'	System	19 Oct 2020 16:15:55

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:17
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'No (N)'	System	19 Oct 2020 16:15:55

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:18
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'No (N)'	System	19 Oct 2020 16:15:55

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:21
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'No (N)'	System	19 Oct 2020 16:15:55



US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'No (N)'	System	19 Oct 2020 16:15:55

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:26
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'Yes (Y)'	System	19 Oct 2020 16:15:55

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:28
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'Lindsey'	System	19 Oct 2020 16:15:55

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'Baden'	System	19 Oct 2020 16:15:55

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'MA'	System	19 Oct 2020 16:15:55

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 13:55:54
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:04:00
User entered 'US'	System	19 Oct 2020 16:21:23

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '3'	System	11 Feb 2021 15:11:17
User entered '2'	System	02 Nov 2020 13:56:05
User entered '1'	System	19 Oct 2020 16:21:23

**US3432242**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000006**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:37:31**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '19/Oct/2020 12:21'	System	19 Oct 2020 16:21:23



US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:37:31

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 13:55:54
User entered 'I'	(b) (4), (b) (6)	19 Oct 2020 16:21:23

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:11
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'USA-US078-2020-MRNA-1273-P301000006'	System	19 Oct 2020 16:15:55

**US3432242**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:37:31**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:13
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'Yes (Y)'	System	19 Oct 2020 16:15:55

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

Death

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:15
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'No (N)'	System	19 Oct 2020 16:15:55

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:17
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'No (N)'	System	19 Oct 2020 16:15:55

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:18
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'No (N)'	System	19 Oct 2020 16:15:55

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:21
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'No (N)'	System	19 Oct 2020 16:15:55

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'No (N)'	System	19 Oct 2020 16:15:55



US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:26
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'Yes (Y)'	System	19 Oct 2020 16:15:55

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:28
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'Lindsey'	System	19 Oct 2020 16:15:55

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'Baden'	System	19 Oct 2020 16:15:55

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'MA'	System	19 Oct 2020 16:15:55

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 13:55:54
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:04:00
User entered 'US'	System	19 Oct 2020 16:21:23

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '3'	System	11 Feb 2021 15:11:17
User entered '2'	System	02 Nov 2020 13:56:05
User entered '1'	System	19 Oct 2020 16:21:23

**US3432242**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000006**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:37:31**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '02/Nov/2020 13:56'	System	02 Nov 2020 13:56:05

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:37:31

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
Reviewed for Safety.	(b) (4), (b) (6)	11 Feb 2021 15:10:49
User entered 'I'	(b) (4), (b) (6)	02 Nov 2020 13:56:05



US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:11
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'USA-US078-2020-MRNA-1273-P301000006'	System	19 Oct 2020 16:15:55

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:13
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'Yes (Y)'	System	19 Oct 2020 16:15:55

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

Death

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:15
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'No (N)'	System	19 Oct 2020 16:15:55

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:17
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'No (N)'	System	19 Oct 2020 16:15:55

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:18
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'No (N)'	System	19 Oct 2020 16:15:55

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:21
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'No (N)'	System	19 Oct 2020 16:15:55

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:23
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'No (N)'	System	19 Oct 2020 16:15:55

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:26
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'Yes (Y)'	System	19 Oct 2020 16:15:55



US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:28
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'Lindsey'	System	19 Oct 2020 16:15:55

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:31
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'Baden'	System	19 Oct 2020 16:15:55

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:03:58
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 16:20:52
User entered 'MA'	System	19 Oct 2020 16:15:55

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 13:55:54
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:04:00
User entered 'US'	System	19 Oct 2020 16:21:23

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 17:37:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '3'	System	11 Feb 2021 15:11:17
User entered '2'	System	02 Nov 2020 13:56:05
User entered '1'	System	19 Oct 2020 16:21:23

**US3432242**

**Folder: SAE USA-US078-2020-MRNA-1273-P301000006**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 17:37:31**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered '11/Feb/2021 10:11'	System	11 Feb 2021 15:11:17

US3432242

Folder: SAE USA-US078-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:37:31

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:08:53
User entered 'I'	(b) (4), (b) (6)	11 Feb 2021 15:11:17