

US3432627 (Prod: Brigham and Womens Hospital)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:41:33

All time stamps listed in this document are displayed in GMT

US3432627

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 03:35:07

Generated On: 09 Jun 2021 17:41:33

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[Participant ID](#)

US3432627

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

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US3432627

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 03:35:18

Generated On: 09 Jun 2021 17:41:33

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

Visit date (dd MMM yyyy)	21 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3432627

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 03:35:18

Generated On: 09 Jun 2021 17:41:33

Date of Birth (MMM yyyy)	(b) (6) 1987
Age	33
Age Units	YEARS
Age (Derived)	33
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	True
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 03:35:18

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	21 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input checked="" 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 03:35:18

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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 03:35:18

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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 03:35:18

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Condition	MILD ASTHMA
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
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 03:35:18

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Condition	TRAUMATIC BRAIN INJURY
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 03:35:18

Generated On: 09 Jun 2021 17:41:33

Condition	MIGRAINES
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 03:35:18

Generated On: 09 Jun 2021 17:41:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	21 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	11:12 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 11:12
Height ( <i>xxx.x</i> )	156 cm
Weight ( <i>xxx.x</i> )	67.0 kg
BMI ( <i>xxx.x</i> )	27.53123 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 03:35:18

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 OCT 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 03:35:18

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Date of assessment (dd MMM yyyy) 21 OCT 2020

Is the participant of childbearing potential? Yes ☒  
No ☐

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

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

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 03:35:18

Generated On: 09 Jun 2021 17:41:33

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	21 OCT 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	11:25
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 03:35:18

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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 03:35:18

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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 03:35:18

Generated On: 09 Jun 2021 17:41:33

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

Visit date (dd MMM yyyy)	21 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 03:35:18

Generated On: 09 Jun 2021 17:41:33

What was the date of randomization? (dd MMM yyyy) 21 OCT 2020

What was the participant's randomization number? 117660

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 03:35:18

Generated On: 09 Jun 2021 17:41:33

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 03:35:18

Generated On: 09 Jun 2021 17:41:33

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)	21 OCT 2020
Time of assessment (00:00-23:59)	11:12 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 11:12
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 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 03:35:18

Generated On: 09 Jun 2021 17:41:33

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)	21 OCT 2020
Time of assessment (00:00-23:59)	12:35 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 12:35
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 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 03:35:18

Generated On: 09 Jun 2021 17:41:33

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 03:35:18

Generated On: 09 Jun 2021 17:41:33

Was the pregnancy test performed? Yes ☒  
No ☐

Date of test (dd MMM yyyy) 21 OCT 2020

Test performed Urine ☒  
Serum ☐

Result Positive ☐  
Negative ☒

Was FSH sample collected? Yes ☐  
No ☒

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 03:35:18

Generated On: 09 Jun 2021 17:41:33

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 OCT 2020

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

Treatment Date and Time (derived) 21 OCT 2020 11:59

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 03:35:18

Generated On: 09 Jun 2021 17:41:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 OCT 2020
Collection time (00:00-23:59)	11:38 (24 HR)
Collection date and time (derived)	21 OCT 2020 11:38

US3432627

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 03:35:18

Generated On: 09 Jun 2021 17:41:33

Collection date (dd MMM yyyy)			21 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:45	21 OCT 2020 11:45
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:35:18

Generated On: 09 Jun 2021 17:41:33

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 17:41:33

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 OCT 2020 12:37

PC Open Date & Time

21 OCT 2020 12:19

PC Close Date & Time

21 OCT 2020 14:49

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

**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 96.9 °F

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

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

PC Time Stamp	21 OCT 2020 20:48
PC Open Date & Time	21 OCT 2020 15:44
PC Close Date & Time	22 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:41:33

**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

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

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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 OCT 2020 18:53

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.3 °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 OCT 2020 11:22

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59



US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:41:33

**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

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

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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 OCT 2020 19:49

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

**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 ☐

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

80

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 - **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 OCT 2020 12:38

PC Open Date & Time

21 OCT 2020 12:19

PC Close Date & Time

21 OCT 2020 14:49

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

**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)

2

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

21 OCT 2020 20:50

PC Open Date & Time

21 OCT 2020 15:44

PC Close Date & Time

22 OCT 2020 11:59

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:41:33

**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 ☐

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

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:41:33

**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

23 OCT 2020 18:51

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:41:33

**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

25 OCT 2020 11:20

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59



US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:41:33

**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 ☐

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

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:41:33

**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

26 OCT 2020 19:49

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:41:33

**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 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

**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 ☐

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

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

No ☒

Yes ☐

PC Time stamp	21 OCT 2020 12:39
PC Open Date & Time	21 OCT 2020 12:19
PC Close Date & Time	21 OCT 2020 14:49

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

**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 ☐

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

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

No ☒

Yes ☐

PC Time stamp	21 OCT 2020 20:50
PC Open Date & Time	21 OCT 2020 15:44
PC Close Date & Time	22 OCT 2020 11:59

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:33

**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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Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:33

Yes ☐

PC Time stamp

PC Open Date & Time

22 OCT 2020 12:00

PC Close Date & Time

23 OCT 2020 11:59

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:33

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 ☒

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:33

Yes <input type="checkbox"/>	
PC Time stamp	23 OCT 2020 18:54
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:33

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 ☒

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:33

Yes <input type="checkbox"/>	
PC Time stamp	25 OCT 2020 11:20
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:33

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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Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:33

Yes ☐

PC Time stamp

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:33

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

55 of 1890



US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:33

Yes <input type="checkbox"/>	
PC Time stamp	26 OCT 2020 19:49
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:33

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)

57 of 1890

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:33

Yes ☐

PC Time stamp

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3432627

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☐

**HEADACHE**

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 ☐

PC Time Stamp

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3432627

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:41:33

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	28 OCT 2020 12:00
PC Close Date & Time	29 OCT 2020 11:59

US3432627

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:35:18

Generated On: 09 Jun 2021 17:41:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3432627

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:35:18

Generated On: 09 Jun 2021 17:41:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432627

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:35:07

Generated On: 09 Jun 2021 17:41:33

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 4 NOV 2020

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

Comments

*If Contact Not Made, please provide Comments*



US3432627

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:35:07

Generated On: 09 Jun 2021 17:41:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432627

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:35:07

Generated On: 09 Jun 2021 17:41:33

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3432627

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:35:07

Generated On: 09 Jun 2021 17:41:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432627

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 03:35:18

Generated On: 09 Jun 2021 17:41:33

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

Visit date (dd MMM yyyy)	18 NOV 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3432627

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 03:35:18

Generated On: 09 Jun 2021 17:41:33

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)	18 NOV 2020
Time of assessment (00:00-23:59)	12:50 (24 HR)
Vital Signs Date and Time (derived)	18 NOV 2020 12:50
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	100 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3432627

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 03:35:18

Generated On: 09 Jun 2021 17:41:33

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)	18 NOV 2020
Time of assessment (00:00-23:59)	14:50 (24 HR)
Vital Signs Date and Time (derived)	18 NOV 2020 14:50
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3432627

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 03:35:18

Generated On: 09 Jun 2021 17:41:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 NOV 2020

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

US3432627

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 03:35:18

Generated On: 09 Jun 2021 17:41:33

Was the pregnancy test performed? Yes ☒  
No ☐

Date of test (dd MMM yyyy) 18 NOV 2020

Test performed Urine ☒  
Serum ☐

Result Positive ☐  
Negative ☒

Was FSH sample collected? Yes ☐  
No ☒

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



US3432627

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 03:35:18

Generated On: 09 Jun 2021 17:41:33

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) 18 NOV 2020

What was the treatment time? (00:00-23:59) 14:17 (24 HR)

Treatment Date and Time (derived) 18 NOV 2020 14:17

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

What was the frequency of the study treatment dosing? ONCE

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

US3432627

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 03:35:18

Generated On: 09 Jun 2021 17:41:33

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 NOV 2020

Collection time (00:00-23:59)

13:40 (24 HR)

Collection date and time (derived)

18 NOV 2020 13:40

US3432627

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 03:35:18

Generated On: 09 Jun 2021 17:41:33

Collection date (dd MMM yyyy)			18 NOV 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:05	18 NOV 2020 14:05
Nasopharyngeal Swab 2	No		

US3432627

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:35:18

Generated On: 09 Jun 2021 17:41:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

**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

18 NOV 2020 14:51

PC Open Date & Time

18 NOV 2020 14:37

PC Close Date & Time

18 NOV 2020 17:07

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

**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 ☒

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

Yes ☐

No ☒

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

PC Time Stamp 18 NOV 2020 18:45

PC Open Date & Time 18 NOV 2020 18:02

PC Close Date & Time 19 NOV 2020 11:59

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:41:33

**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

99.6 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

19 NOV 2020 14:28

PC Open Date & Time

19 NOV 2020 12:00

PC Close Date & Time

20 NOV 2020 11:59

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:41:33

**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

20 NOV 2020 12:00

PC Close Date & Time

21 NOV 2020 11:59



US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:41:33

**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

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

21 NOV 2020 12:00

PC Close Date & Time

22 NOV 2020 11:59

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:41:33

**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

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

22 NOV 2020 12:00

PC Close Date & Time

23 NOV 2020 11:59

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:41:33

**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.

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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

23 NOV 2020 12:00

PC Close Date & Time

24 NOV 2020 11:59

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:41:33

**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

24 NOV 2020 12:00

PC Close Date & Time

25 NOV 2020 11:59

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

**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

18 NOV 2020 14:51

PC Open Date & Time

18 NOV 2020 14:37

PC Close Date & Time

18 NOV 2020 17:07

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

18 NOV 2020 19:01

PC Open Date & Time

18 NOV 2020 18:02

PC Close Date & Time

19 NOV 2020 11:59

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:41:33

**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

19 NOV 2020 14:28

PC Open Date & Time

19 NOV 2020 12:00

PC Close Date & Time

20 NOV 2020 11:59

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:41:33

**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

20 NOV 2020 12:00

PC Close Date & Time

21 NOV 2020 11:59



US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:41:33

**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 ☐

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

21 NOV 2020 12:00

PC Close Date & Time

22 NOV 2020 11:59

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:41:33

**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 ☐

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

22 NOV 2020 12:00

PC Close Date & Time

23 NOV 2020 11:59

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:41:33

**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 ☐

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 NOV 2020 12:00

PC Close Date & Time

24 NOV 2020 11:59

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:41:33

**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

24 NOV 2020 12:00

PC Close Date & Time

25 NOV 2020 11:59

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

**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 ☐

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

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

No ☒

Yes ☐

PC Time stamp	18 NOV 2020 14:51
PC Open Date & Time	18 NOV 2020 14:37
PC Close Date & Time	18 NOV 2020 17:07

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

**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 ☐

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

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

No ☒

Yes ☐

PC Time stamp	18 NOV 2020 19:01
PC Open Date & Time	18 NOV 2020 18:02
PC Close Date & Time	19 NOV 2020 11:59



US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:33

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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Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:33

Yes <input type="checkbox"/>	
PC Time stamp	19 NOV 2020 14:29
PC Open Date & Time	19 NOV 2020 12:00
PC Close Date & Time	20 NOV 2020 11:59

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:33

**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 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:33

Yes ☐

PC Time stamp

PC Open Date & Time

20 NOV 2020 12:00

PC Close Date & Time

21 NOV 2020 11:59

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:33

**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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Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:33

Yes ☐

PC Time stamp

PC Open Date & Time

21 NOV 2020 12:00

PC Close Date & Time

22 NOV 2020 11:59

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:33

**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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Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:33

Yes ☐

PC Time stamp

PC Open Date & Time

22 NOV 2020 12:00

PC Close Date & Time

23 NOV 2020 11:59



US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:33

**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 17:41:33

Yes ☐

PC Time stamp

PC Open Date & Time

23 NOV 2020 12:00

PC Close Date & Time

24 NOV 2020 11:59

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

**DAY 7**

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

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Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:33

Yes ☐

PC Time stamp

PC Open Date & Time

24 NOV 2020 12:00

PC Close Date & Time

25 NOV 2020 11:59

US3432627

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:35:18

Generated On: 09 Jun 2021 17:41:33

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 NOV 2020

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

Comments PT CALLED AT 8:40 AND 12:11  
ON 25NOV2020 AND 9:49 AND  
1:53 ON 27NOV2020.  
*If Contact Not Made, please provide Comments*

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Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:35:18

Generated On: 09 Jun 2021 17:41:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432627

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:35:18

Generated On: 09 Jun 2021 17:41:33

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3432627

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:35:18

Generated On: 09 Jun 2021 17:41:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3432627

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:35:18

Generated On: 09 Jun 2021 17:41:33

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 DEC 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3432627

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:35:18

Generated On: 09 Jun 2021 17:41:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432627

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 03:35:18

Generated On: 09 Jun 2021 17:41:33

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

Visit date (dd MMM yyyy)	17 DEC 2020
--------------------------	-------------

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

Folder OID	VISIT3
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US3432627

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 03:35:18

Generated On: 09 Jun 2021 17:41:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 DEC 2020
Time of assessment (00:00-23:59)	15:04 (24 HR)
Vital Signs Date and Time (derived)	17 DEC 2020 15:04
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	073 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432627

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 03:35:18

Generated On: 09 Jun 2021 17:41:33

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.*

US3432627

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 03:35:18

Generated On: 09 Jun 2021 17:41:33

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 DEC 2020

Collection time (00:00-23:59)

15:25 (24 HR)

Collection date and time (derived)

17 DEC 2020 15:25

US3432627

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:35:18

Generated On: 09 Jun 2021 17:41:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

TIMEPOINT	DAY 61
Have 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 14:36:44
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59



US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

DAY 68

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 21:30:18

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 JAN 2021 11:59:29
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 JAN 2021 14:21:40

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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	18 JAN 2021 10:32:41
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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	24 JAN 2021 17:58:09
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**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

01 FEB 2021 16:03:13

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 FEB 2021 20:14:35

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	13 FEB 2021 20:56:37
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59



US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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	22 FEB 2021 18:04:03
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**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

02 MAR 2021 12:13:23

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**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

07 MAR 2021 13:28:18

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

<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	12 MAR 2021 12:24:33
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**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 MAR 2021 18:40:36

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	29 MAR 2021 17:06:19
Patient Cloud Open Date & Time	26 MAR 2021 00:01
Patient Cloud Close Date & Time	30 MAR 2021 23:59

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	05 APR 2021 17:41:21
Patient Cloud Open Date & Time	02 APR 2021 00:01
Patient Cloud Close Date & Time	06 APR 2021 23:59

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**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

09 APR 2021 15:54:59

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59



US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 APR 2021 11:09:28
Patient Cloud Open Date & Time	16 APR 2021 00:01
Patient Cloud Close Date & Time	20 APR 2021 23:59

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 12:03:32

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	30 APR 2021 13:00:21
Patient Cloud Open Date & Time	30 APR 2021 00:01
Patient Cloud Close Date & Time	04 MAY 2021 23:59

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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="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"/>

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Close Date & Time](#)

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18 MAY 2021 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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 <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"/>



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Close Date & Time](#)

---

25 MAY 2021 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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 <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"/>

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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 <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"/>

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	02 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 JUL 2021 23:59

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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"/>



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**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 ☐

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	23 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 JUL 2021 23:59

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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"/>

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	30 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 AUG 2021 23:59

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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="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"/>

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Open Date & Time](#)

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13 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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17 AUG 2021 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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"/>

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 AUG 2021 23:59

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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"/>

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

DAY 327

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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"/>

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Close Date & Time](#)

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21 SEP 2021 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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"/>

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 OCT 2021 23:59

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**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 ☐



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**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 ☐

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**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 ☐

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Open Date & Time](#)

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29 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 NOV 2021 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**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 ☐



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Close Date & Time](#)

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09 NOV 2021 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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

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

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Open Date & Time](#)

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19 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 NOV 2021 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Open Date & Time](#)

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26 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 NOV 2021 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

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

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

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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"/>

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

31 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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"/>

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Close Date & Time](#)

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11 JAN 2022 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**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 ☐

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 JAN 2022 23:59

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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"/>

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 JAN 2022 23:59

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

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

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

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Close Date & Time](#)

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22 FEB 2022 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**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 ☐ Yes ☐

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



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Close Date & Time](#)

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01 MAR 2022 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**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 ☐

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Close Date & Time](#)

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08 MAR 2022 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**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 ☐

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Open Date & Time](#)

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18 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 MAR 2022 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**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 ☐



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Open Date & Time](#)

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25 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 MAR 2022 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 APR 2022 23:59

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**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 ☐

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Open Date & Time](#)

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08 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 APR 2022 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

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

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

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**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 ☐



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 APR 2022 23:59

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Open Date & Time](#)

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29 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 MAY 2022 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**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 ☐

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Close Date & Time](#)

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10 MAY 2022 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**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°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 ☐

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Open Date & Time](#)

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13 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAY 2022 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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 <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"/>



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Open Date & Time](#)

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20 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAY 2022 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**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 ☐

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Open Date & Time](#)

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27 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAY 2022 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Open Date & Time](#)

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03 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 JUN 2022 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Close Date & Time](#)

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14 JUN 2022 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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"/>



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Close Date & Time](#)

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21 JUN 2022 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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"/>

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Open Date & Time](#)

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24 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 JUN 2022 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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"/>

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Open Date & Time](#)

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01 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 JUL 2022 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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"/>

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Close Date & Time](#)

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12 JUL 2022 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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"/>



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Open Date & Time](#)

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29 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 AUG 2022 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Open Date & Time](#)

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05 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 AUG 2022 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**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 ☐



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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"/>

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Open Date & Time](#)

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19 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 AUG 2022 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**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 ☐

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	26 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	30 AUG 2022 23:59
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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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"/>

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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"/>

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Close Date & Time](#)

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20 SEP 2022 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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"/>

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Close Date & Time](#)

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04 OCT 2022 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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"/>



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

DAY 726

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

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

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

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

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

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

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

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

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**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 ☐

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Close Date & Time](#)

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25 OCT 2022 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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"/>

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Close Date & Time](#)

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01 NOV 2022 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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"/>



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Close Date & Time](#)

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08 NOV 2022 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Open Date & Time](#)

11 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 NOV 2022 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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="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"/>

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 NOV 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 NOV 2022 23:59

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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"/>

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

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[Patient Cloud Close Date & Time](#)

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29 NOV 2022 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**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 ☐



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	02 DEC 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 DEC 2022 23:59

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	09 DEC 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 DEC 2022 23:59

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

**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°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 ☐

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

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16 DEC 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 DEC 2022 23:59

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US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

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

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	23 DEC 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 DEC 2022 23:59

US3432627

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:41:33

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 12:13:32



US3432627

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:35:18

Generated On: 09 Jun 2021 17:41:33

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 JAN 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3432627

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:35:18

Generated On: 09 Jun 2021 17:41:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432627

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:35:07

Generated On: 09 Jun 2021 17:41:33

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3432627

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:35:07

Generated On: 09 Jun 2021 17:41:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432627

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 21:11:43

Generated On: 09 Jun 2021 17:41:33

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3432627

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 21:11:43

Generated On: 09 Jun 2021 17:41:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432627

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 25 Apr 2021 11:30:22

Generated On: 09 Jun 2021 17:41:33

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 APR 2021

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

Comments

*If Contact Not Made, please provide Comments*

ATTEMPTED TO CONTACT PT  
FOR SAFETY CALL - CONTACT  
WAS NOT MADE. PT WAS  
CALLED 14APR21 @14:17,  
16APR21 @10:38 AND 19APR21  
@11:58

US3432627

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 25 Apr 2021 11:30:22

Generated On: 09 Jun 2021 17:41:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



**US3432627**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:41:33**

Was this visit performed? Yes ☐  
No ☐

Visit date (dd MMM yyyy) \_\_\_\_\_

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

Folder OID \_\_\_\_\_

US3432627

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:33

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment ( <i>dd MMM yyyy</i> )	
Time of assessment ( <i>00:00-23:59</i> )	
Vital Signs Date and Time (derived)	
Temperature ( <i>xxx.x</i> )	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse ( <i>xxx</i> )	
Pulse units	
Respiratory Rate ( <i>xxx</i> )	
Respiratory Rate units	
Systolic Blood Pressure ( <i>xxx</i> )	
Systolic Blood Pressure units	
Diastolic Blood Pressure ( <i>xxx</i> )	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3432627

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:33

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.*

US3432627

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:33

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

Collection date ( <i>dd MMM yyyy</i> )	_____
Collection time ( <i>00:00-23:59</i> )	_____
Collection date and time (derived)	_____

**US3432627**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:41:33**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3432627

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:41:33

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

**US3432627**

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

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

**Generated On: 09 Jun 2021 17:41:33**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3432627

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 03:35:07

Generated On: 09 Jun 2021 17:41:33

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

Visit date (dd MMM yyyy)	23 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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US3432627

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

Form: Unblinding

Data signed: (b) (4) 25 Apr 2021 11:30:22

Generated On: 09 Jun 2021 17:41:33

Date of updated informed consent (dd MMM yyyy) 23 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) 23 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 \_\_\_\_\_

US3432627

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 03:35:07

Generated On: 09 Jun 2021 17:41:33

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

Collection date (dd MMM yyyy)	23 JAN 2021
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Collection time (00:00-23:59)	11:30 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	23 JAN 2021 11:30
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US3432627

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 03:35:07

Generated On: 09 Jun 2021 17:41:33

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 JAN 2021

Collection time (00:00 - 23:59)

11:46

Collection Date and Time (derived)

23 JAN 2021 11:46

US3432627

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 03:35:07

Generated On: 09 Jun 2021 17:41:33

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3432627

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 04 Apr 2021 21:11:43

Generated On: 09 Jun 2021 17:41:33

AEID

Adverse event

LEFT ARM PRURITUS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

21 OCT 2020

Start time (00:00-23:59)

12:20 (24 HR)

AE start date and time (derived)

21 OCT 2020 12:20

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

21 OCT 2020

End time (00:00-23:59)

17:45 (24 HR)

AE End Date and Time (derived)

21 OCT 2020 17:45

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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EAB) (1725)

US3432627

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 04 Apr 2021 21:11:43

Generated On: 09 Jun 2021 17:41:33

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

US3432627

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 04 Apr 2021 21:11:43

Generated On: 09 Jun 2021 17:41:33

AEID	USA-US078-2020-MRNA-1273-P30 1000014
Adverse event	HERNIA S/P LEFT INGUINAL HERNIA REPAIR
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)	23 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	24 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	23 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	24 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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US3432627

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 04 Apr 2021 21:11:43

Generated On: 09 Jun 2021 17:41:33

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
PARTICIPANT SEEN AND ADMITTED FOR HERNIA REPAIR. PARTICIPANT DISCHARGED ON 24NOV2020.	
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0
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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 04 Apr 2021 21:11:43

Generated On: 09 Jun 2021 17:41:33

AEID	
Adverse event	UTI
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)	30 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 04 Apr 2021 21:11:43

Generated On: 09 Jun 2021 17:41:33

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

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 03:35:07

Generated On: 09 Jun 2021 17:41:33

---

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

Yes ☒

No ☐

---

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

---

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 04 Apr 2021 21:11:43

Generated On: 09 Jun 2021 17:41:33

Name of Medication ALBUTEROL

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 04 Apr 2021 21:11:43

Generated On: 09 Jun 2021 17:41:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 04 Apr 2021 21:11:43

Generated On: 09 Jun 2021 17:41:33

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 04 Apr 2021 21:11:43

Generated On: 09 Jun 2021 17:41:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 19 NOV 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 04 Apr 2021 21:11:43

Generated On: 09 Jun 2021 17:41:33

Name of Medication OXYCODONE

Prophylaxis Yes ☐  
No ☒

Indication PAIN AFTER LEFT INGUINAL  
HERNIA REPAIR

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 04 Apr 2021 21:11:43

Generated On: 09 Jun 2021 17:41:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	23 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	28 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 04 Apr 2021 21:11:43

Generated On: 09 Jun 2021 17:41:33

Name of Medication CELECOXIB

Prophylaxis Yes ☐  
No ☒

Indication PAIN FROM HERNIA REPAIR

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 04 Apr 2021 21:11:43

Generated On: 09 Jun 2021 17:41:33

	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)		23 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 23 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 04 Apr 2021 21:11:43

Generated On: 09 Jun 2021 17:41:33

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication PAIN FROM HERNIA REPAIR

Dose per administration 975

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 04 Apr 2021 21:11:43

Generated On: 09 Jun 2021 17:41:33

	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)		23 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 23 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 04 Apr 2021 21:11:43

Generated On: 09 Jun 2021 17:41:33

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication PAIN FROM HERNIA REPAIR

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Q8 HOURS FOR 4 DAYS THEN  
UP TO 3 TIMES A DAY

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 04 Apr 2021 21:11:43

Generated On: 09 Jun 2021 17:41:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	24 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		2 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 04 Apr 2021 21:11:43

Generated On: 09 Jun 2021 17:41:33

Name of Medication CEFUROXIME

Prophylaxis Yes ☐  
No ☒

Indication UTI

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 (8)

Data signed: (b) (4) 04 Apr 2021 21:11:43

Generated On: 09 Jun 2021 17:41:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	30 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 04 Apr 2021 21:11:43

Generated On: 09 Jun 2021 17:41:33

Name of Medication VITAMIN D

Prophylaxis Yes ☐  
No ☒

Indication GENERAL HEALTH

Dose per administration 50,000

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

If dose unit is Other, specify UNITS

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 04 Apr 2021 21:11:43

Generated On: 09 Jun 2021 17:41:33

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

US3432627

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 03:35:07

Generated On: 09 Jun 2021 17:41:33

---

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) 19 Feb 2021 03:35:07

Generated On: 09 Jun 2021 17:41:33

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
23 NOV 2020	HERNIA REPAIR	Adverse Event	

US3432627

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:41:33

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 17:41:33

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 ☐

US3432627

Folder: SAE USA-US078-2020-MRNA-1273-P301000014

Form: Safety Report Form

Data signed: (b) (4) 19 Feb 2021 03:35:07

Generated On: 09 Jun 2021 17:41:33

SAEID	USA-US078-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	1



US3432627

Folder: SAE USA-US078-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Data signed: (b) (4) 19 Feb 2021 03:35:07

Generated On: 09 Jun 2021 17:41:33

SAEID	USA-US078-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	1
Date of submission (Pre-filled from custom function)	25/NOV/2020 13:04
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3432627 (Prod: Brigham and Womens Hospital)

**US3432627**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:41:33**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered 'US3432627'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Oct 2020 15:34:21

US3432627

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:41:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	21 Oct 2020 17:54:54

US3432627

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '21 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Oct 2020 15:34:22

US3432627

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Clinic (Clinic)'	Julia Klopfer (b) (4)	21 Oct 2020 17:54:54

**US3432627**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:41:33**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User entered 'SCRN'	System	21 Oct 2020 17:54:54

US3432627

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:33

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User closed query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity sample collected for Visit 1 Day 1, the Birth Year is missing, however, the CRF has Year of Birth recorded as 1987. Please clarify the subject's Year of Birth and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 10:51:11
Query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity sample collected for Visit 1 Day 1, the Birth Year is missing, however, the CRF has Year of Birth recorded as 1987. Please clarify the subject's Year of Birth and update as appropriate.' answered with 'This is correctly reflected on PPD' (Site from DM).	Jun Bai Park Chang (b) (4)	11 Nov 2020 16:48:34
User opened query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity sample collected for Visit 1 Day 1, the Birth Year is missing, however, the CRF has Year of Birth recorded as 1987. Please clarify the subject's Year of Birth and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 18:15:34
User entered (b) (6) 1987'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Oct 2020 15:34:24



US3432627

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:33

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '33'	Julia Klopfer (b) (4)	21 Oct 2020 17:56:44

**US3432627**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:41:33**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User entered 'YEARS'	System	21 Oct 2020 17:56:44

**US3432627**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:41:33**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User entered '33'	System	21 Oct 2020 15:38:46

US3432627

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:33

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User closed query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity sample collected for Visit 1 Day 1 has no data recorded for the subject's sex, however, the CRF has Sex recorded as Female. Please clarify the subject's Sex and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 10:15:02
Query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity sample collected for Visit 1 Day 1 has no data recorded for the subject's sex, however, the CRF has Sex recorded as Female. Please clarify the subject's Sex and update if appropriate.' answered with 'This is correctly reflected on PPD' (Site from DM).	Jun Bai Park Chang (b) (4)	11 Nov 2020 16:48:38
User opened query 'Per GCL Lab Reconciliation: Per GCL, the immunogenicity sample collected for Visit 1 Day 1 has no data recorded for the subject's sex, however, the CRF has Sex recorded as Female. Please clarify the subject's Sex and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 21:05:41
User entered 'Female (F)'	Julia Klopfer (b) (4) (b) (4)	21 Oct 2020 17:56:44

US3432627

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:33

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Julia Klopfer (b) (4)	21 Oct 2020 17:56:44

US3432627

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:33

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'I'	Julia Klopfer (b) (4)	21 Oct 2020 17:56:44

US3432627

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:33

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '0'	Julia Klopfer (b) (4)	21 Oct 2020 17:56:44

US3432627

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:33

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '0'	Julia Klopfer (b) (4)	21 Oct 2020 17:56:44



US3432627

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:33

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'I'	Julia Klopfer (b) (4)	21 Oct 2020 17:56:44

US3432627

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:33

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '0'	Julia Klopfer (b) (4)	21 Oct 2020 17:56:44

US3432627

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:33

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '0'	Julia Klopfer (b) (4)	21 Oct 2020 17:56:44

US3432627

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:33

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered empty.	Julia Klopfer (b) (4)	21 Oct 2020 17:56:44

US3432627

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:33

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '0'	Julia Klopfer (b) (4)	21 Oct 2020 17:56:44

US3432627

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:41:33

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '0'	Julia Klopfer (b) (4)	21 Oct 2020 17:56:44

US3432627

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:41:33

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '21 Oct 2020'	Julia Klopfer (b) (4)	21 Oct 2020 15:38:46

US3432627

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User entered 'Oct 2020'	System	21 Oct 2020 15:38:46



US3432627

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User entered '2020'	System	21 Oct 2020 15:38:46

US3432627

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:41:33

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Amendment 4 (4)'	Julia Klopfer (b) (4)	21 Oct 2020 15:38:46

US3432627

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	21 Oct 2020 15:38:46

US3432627

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:41:33

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered empty.	Julia Klopfer (b) (4)	21 Oct 2020 15:38:46

US3432627

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:41:33

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered empty.	Julia Klopfer (b) (4)	21 Oct 2020 15:38:46

US3432627

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:41:33

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'No (N)'	Julia Klopfer (b) (4)	21 Oct 2020 15:38:46

US3432627

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:41:33

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	21 Oct 2020 15:34:22

US3432627

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:41:33

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User entered 'I'	System	21 Oct 2020 15:38:51



US3432627

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	21 Oct 2020 15:38:51

US3432627

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:41:33

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	21 Oct 2020 17:58:20

US3432627

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:41:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4)	21 Oct 2020 17:59:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Oct 2020 17:59:45
Data point term sent to Coder	System	21 Oct 2020 17:58:57
User entered 'mild asthma'	Julia Klopfer (b) (4)	21 Oct 2020 17:58:51

US3432627

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'un UNK 2012'	Julia Klopfer (b) (4)	21 Oct 2020 17:58:51

US3432627

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:41:33

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '0'	Julia Klopfer (b) (4)	21 Oct 2020 17:58:51

US3432627

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:41:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	21 Oct 2020 17:58:51

US3432627

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:41:33

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered empty.	Julia Klopfer (b) (4)	21 Oct 2020 17:58:51

US3432627

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:41:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '0'	Julia Klopfer (b) (4)	21 Oct 2020 17:58:51



US3432627

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:41:33

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User entered 'Jan 2012'	System	21 Oct 2020 17:58:51

**US3432627**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:41:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User entered '2012'	System	21 Oct 2020 17:58:51

US3432627

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User entered empty.	System	21 Oct 2020 17:58:51

**US3432627**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:41:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User entered empty.	System	21 Oct 2020 17:58:51

US3432627

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:41:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Cerebral injuries NEC, PT: Craniocerebral injury, LLT: Traumatic brain injury - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 18:00:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 18:00:33
Data point term sent to Coder	System	21 Oct 2020 17:59:58
User entered 'traumatic brain injury'	Julia Klopfer (b) (4)	21 Oct 2020 17:59:12

US3432627

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'un UNK 2010'	Julia Klopfer (b) (4)	21 Oct 2020 17:59:12

US3432627

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:41:33

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '0'	Julia Klopfer (b) (4)	21 Oct 2020 17:59:12

US3432627

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:41:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	21 Oct 2020 17:59:12



US3432627

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:41:33

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered empty.	Julia Klopfer (b) (4)	21 Oct 2020 17:59:12

US3432627

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:41:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '0'	Julia Klopfer (b) (4)	21 Oct 2020 17:59:12

US3432627

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:41:33

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User entered 'Jan 2010'	System	21 Oct 2020 17:59:12

**US3432627**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:41:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User entered '2010'	System	21 Oct 2020 17:59:12

**US3432627**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:41:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User entered empty.	System	21 Oct 2020 17:59:12

**US3432627**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:41:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User entered empty.	System	21 Oct 2020 17:59:12

US3432627

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:41:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 18:00:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 18:00:34
Data point term sent to Coder	System	21 Oct 2020 17:59:59
User entered 'migraines'	Julia Klopfer (b) (4)	21 Oct 2020 17:59:28

US3432627

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'un UNK 2010'	Julia Klopfer (b) (4)	21 Oct 2020 17:59:28



US3432627

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:41:33

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '0'	Julia Klopfer (b) (4)	21 Oct 2020 17:59:28

**US3432627**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:41:33**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	21 Oct 2020 17:59:28

US3432627

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:41:33

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered empty.	Julia Klopfer (b) (4)	21 Oct 2020 17:59:28

US3432627

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:41:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '0'	Julia Klopfer (b) (4)	21 Oct 2020 17:59:28

**US3432627**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:41:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User entered 'Jan 2010'	System	21 Oct 2020 17:59:28

**US3432627**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:41:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User entered '2010'	System	21 Oct 2020 17:59:28

US3432627

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User entered empty.	System	21 Oct 2020 17:59:28

**US3432627**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:41:33**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User entered empty.	System	21 Oct 2020 17:59:28



US3432627

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	21 Oct 2020 18:00:45

US3432627

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '21 Oct 2020'	Julia Klopfer (b) (4)	21 Oct 2020 18:00:45

US3432627

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:33

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '11:12'	Julia Klopfer (b) (4)	21 Oct 2020 18:00:45

**US3432627**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:41:33**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User entered '21 Oct 2020 11:12'	System	21 Oct 2020 18:00:45

US3432627

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:33

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '156' cm	Julia Klopfer (b) (4)	21 Oct 2020 18:00:45
DataPoint set to visible.	(b) (4) System	21 Oct 2020 15:38:51

US3432627

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:33

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '67.0' kg	Julia Klopfer (b) (4)	21 Oct 2020 18:00:45
DataPoint set to visible.	(b) (4) System	21 Oct 2020 15:38:51

US3432627

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:33

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User entered '27.53123'	System	21 Oct 2020 18:00:45
DataPoint set to visible.	System	21 Oct 2020 15:38:51

**US3432627**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:41:33**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User entered 'kg/m2'	System	21 Oct 2020 18:00:45
DataPoint set to visible.	System	21 Oct 2020 15:38:51



US3432627

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered missing code ND - Not Done.	Julia Klopfer (b) (4)	21 Oct 2020 18:00:45

US3432627

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered empty.	Julia Klopfer (b) (4)	21 Oct 2020 18:00:45

US3432627

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered empty.	Julia Klopfer (b) (4)	21 Oct 2020 18:00:45

US3432627

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered missing code ND - Not Done.	Julia Klopfer (b) (4)	21 Oct 2020 18:00:45

**US3432627**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:41:33**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User entered 'bpm'	System	21 Oct 2020 18:00:45

US3432627

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered missing code ND - Not Done.	Julia Klopfer (b) (4)	21 Oct 2020 18:00:45

US3432627

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User entered 'breaths/min'	System	21 Oct 2020 18:00:45

US3432627

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered missing code ND - Not Done.	Julia Klopfer (b) (4)	21 Oct 2020 18:00:45



**US3432627**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:41:33**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User entered 'mmHg'	System	21 Oct 2020 18:00:45

US3432627

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered missing code ND - Not Done.	Julia Klopfer (b) (4)	21 Oct 2020 18:00:45

**US3432627**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:41:33**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User entered 'mmHg'	System	21 Oct 2020 18:00:45

US3432627

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:33

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08

US3432627

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:33

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08

US3432627

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	21 Oct 2020 18:02:05

US3432627

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:33

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '21 Oct 2020'	Julia Klopfer (b) (4)	21 Oct 2020 18:02:05

US3432627

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:41:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '21 Oct 2020'	Julia Klopfer (b) (4)	21 Oct 2020 18:02:24



US3432627

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:41:33

Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	21 Oct 2020 18:02:24

US3432627

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:41:33

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered empty.	Julia Klopfer (b) (4)	21 Oct 2020 18:02:24

US3432627

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:41:33

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered empty.	Julia Klopfer (b) (4)	21 Oct 2020 18:02:24

US3432627

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:41:33

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered empty.	Julia Klopfer (b) (4)	21 Oct 2020 18:02:24

US3432627

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:41:33

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '0'	Julia Klopfer (b) (4)	21 Oct 2020 18:02:24

US3432627

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:41:33

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered empty.	Julia Klopfer (b) (4)	21 Oct 2020 18:02:24

US3432627

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:41:33

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '0'	Julia Klopfer (b) (4)	21 Oct 2020 18:02:24

US3432627

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:33

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	21 Oct 2020 18:02:41



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Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:33

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '21 Oct 2020'	Julia Klopfer (b) (4)	21 Oct 2020 18:02:41

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Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:33

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Urine (URINE)'	Julia Klopfer (b) (4)	21 Oct 2020 18:02:41

**US3432627**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:41:33**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Negative (NEGATIVE)'	Julia Klopfer (b) (4)	21 Oct 2020 18:02:41

US3432627

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:33

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'No (N)'	Julia Klopfer (b) (4)	21 Oct 2020 18:02:41

US3432627

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:33

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered empty.	Julia Klopfer (b) (4)	21 Oct 2020 18:02:41

**US3432627**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:41:33**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '11:25'	Julia Klopfer (b) (4)	21 Oct 2020 18:02:41

**US3432627**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 09 Jun 2021 17:41:33**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User entered empty.	System	21 Oct 2020 18:02:41

US3432627

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:33

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'No (N)'	Julia Klopfer (b) (4)	21 Oct 2020 18:04:55



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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:33

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'No (N)'	Julia Klopfer (b) (4)	21 Oct 2020 18:04:55

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:33

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'No (N)'	Julia Klopfer (b) (4)	21 Oct 2020 18:04:55

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:33

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'No (N)'	Julia Klopfer (b) (4)	21 Oct 2020 18:04:55

US3432627

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:33

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'No (N)'	Julia Klopfer (b) (4)	21 Oct 2020 18:04:55

US3432627

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:33

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'No (N)'	Julia Klopfer (b) (4)	21 Oct 2020 18:04:55

US3432627

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:33

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'No (N)'	Julia Klopfer (b) (4)	21 Oct 2020 18:04:55

US3432627

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:33

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'No (N)'	Julia Klopfer (b) (4)	21 Oct 2020 18:04:55

US3432627

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:33

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'No (N)'	Julia Klopfer (b) (4)	21 Oct 2020 18:04:55



US3432627

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:33

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'No (N)'	Julia Klopfer (b) (4)	21 Oct 2020 18:04:55

US3432627

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:33

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	21 Oct 2020 18:04:55

US3432627

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:33

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'No (N)'	Julia Klopfer (b) (4)	21 Oct 2020 18:04:55

US3432627

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:33

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered empty.	Julia Klopfer (b) (4)	21 Oct 2020 18:04:55

US3432627

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:33

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '0'	Julia Klopfer (b) (4)	21 Oct 2020 18:04:55

US3432627

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:33

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '0'	Julia Klopfer (b) (4)	21 Oct 2020 18:04:55

US3432627

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:33

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '0'	Julia Klopfer (b) (4)	21 Oct 2020 18:04:55

US3432627

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:33

**Resides in high density housing** (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '0'	Julia Klopfer (b) (4)	21 Oct 2020 18:04:55



US3432627

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:33

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '0'	Julia Klopfer (b) (4)	21 Oct 2020 18:04:55

US3432627

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:33

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'I'	Julia Klopfer (b) (4)	21 Oct 2020 18:04:55

US3432627

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:33

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '0'	Julia Klopfer (b) (4)	21 Oct 2020 18:04:55

US3432627

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:41:33

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered empty.	Julia Klopfer (b) (4)	21 Oct 2020 18:04:55

US3432627

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:41:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	21 Oct 2020 18:05:28

US3432627

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:41:33

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '21 Oct 2020'	Julia Klopfer (b) (4)	21 Oct 2020 18:05:28

US3432627

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:41:33

[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 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Clinic (Clinic)'	Julia Klopfer (b) (4)	21 Oct 2020 18:05:28

US3432627

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:41:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'VISIT1'	System	21 Oct 2020 18:05:28



US3432627

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '21 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Oct 2020 15:34:37

US3432627

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:41:33

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '117660'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Oct 2020 15:34:37

US3432627

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:41:33

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Oct 2020 15:34:37

US3432627

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:41:33

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 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'No (N)'	Julia Klopfer (b) (4)	21 Oct 2020 18:07:05

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Folder: Visit 1 Day 1

Form: Randomization

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Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'No (N)'	Julia Klopfer (b) (4)	21 Oct 2020 18:07:05

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:41:33

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'No (N)'	Julia Klopfer (b) (4)	21 Oct 2020 18:07:05

US3432627

Folder: Visit 1 Day 1

Form: Randomization

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Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'No (N)'	Julia Klopfer (b) (4)	21 Oct 2020 18:07:05

US3432627

Folder: Visit 1 Day 1

Form: Randomization

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[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'No (N)'	Julia Klopfer (b) (4)	21 Oct 2020 18:07:05



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Folder: Visit 1 Day 1

Form: Randomization

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[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'No (N)'	Julia Klopfer (b) (4)	21 Oct 2020 18:07:05
DataPoint set to visible.	(b) (4) System	21 Oct 2020 15:38:46

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:33

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered missing code ND - Not Done.	Julia Klopfer (b) (4)	21 Oct 2020 18:11:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:33

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered missing code ND - Not Done.	Julia Klopfer (b) (4)	21 Oct 2020 18:11:21

US3432627

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:33

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered missing code ND - Not Done.	Julia Klopfer (b) (4)	21 Oct 2020 18:11:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:33

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered missing code ND - Not Done.	Julia Klopfer (b) (4)	21 Oct 2020 18:11:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User accepted default value 'Pre-Dose (PREDOSE)'	Julia Klopfer (b) (4) (b) (4)	21 Oct 2020 18:11:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:33

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	21 Oct 2020 18:11:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '21 Oct 2020'	Julia Klopfer (b) (4)	21 Oct 2020 18:11:21



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:33

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '11:12'	Julia Klopfer (b) (4)	21 Oct 2020 18:11:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered '21 Oct 2020 11:12'	System	21 Oct 2020 18:11:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '97.7' F	Julia Klopfer (b) (4)	21 Oct 2020 18:11:21

US3432627

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Other (Other)'	Julia Klopfer (b) (4)	21 Oct 2020 18:11:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'infrared'	Julia Klopfer (b) (4)	21 Oct 2020 18:11:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '89'	Julia Klopfer (b) (4)	21 Oct 2020 18:11:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'bpm'	System	21 Oct 2020 18:11:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '16'	Julia Klopfer (b) (4)	21 Oct 2020 18:11:21



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'breaths/min'	System	21 Oct 2020 18:11:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '124'	Julia Klopfer (b) (4)	21 Oct 2020 18:11:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'mmHg'	System	21 Oct 2020 18:11:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '78'	Julia Klopfer (b) (4)	21 Oct 2020 18:11:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'mmHg'	System	21 Oct 2020 18:11:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:33

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered missing code ND - Not Done.	Julia Klopfer (b) (4)	21 Oct 2020 18:11:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:41:33

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered missing code ND - Not Done.	Julia Klopfer (b) (4)	21 Oct 2020 18:11:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User accepted default value 'Post-Dose (POSTDOSE)'	Julia Klopfer (b) (4) (b) (4)	21 Oct 2020 18:11:21



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	21 Oct 2020 18:11:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '21 Oct 2020'	Julia Klopfer (b) (4)	21 Oct 2020 18:11:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:33

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '12:35'	Julia Klopfer (b) (4)	21 Oct 2020 18:11:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered '21 Oct 2020 12:35'	System	21 Oct 2020 18:11:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '97.5' F	Julia Klopfer (b) (4)	21 Oct 2020 18:11:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Other (Other)'	Julia Klopfer (b) (4)	21 Oct 2020 18:11:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'infrared'	Julia Klopfer (b) (4)	21 Oct 2020 18:11:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '83'	Julia Klopfer (b) (4)	21 Oct 2020 18:11:21



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'bpm'	System	21 Oct 2020 18:11:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '14'	Julia Klopfer (b) (4)	21 Oct 2020 18:11:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'breaths/min'	System	21 Oct 2020 18:11:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '121'	Julia Klopfer (b) (4)	21 Oct 2020 18:11:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'mmHg'	System	21 Oct 2020 18:11:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '73'	Julia Klopfer (b) (4)	21 Oct 2020 18:11:21

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'mmHg'	System	21 Oct 2020 18:11:21

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'No (N)'	Julia Klopfer (b) (4)	21 Oct 2020 18:11:32



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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered empty.	Julia Klopfer (b) (4)	21 Oct 2020 18:11:32

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:33

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	21 Oct 2020 18:11:52

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:33

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '21 Oct 2020'	Julia Klopfer (b) (4)	21 Oct 2020 18:11:52

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:33

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Urine (URINE)'	Julia Klopfer (b) (4)	21 Oct 2020 18:11:52

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:33

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Negative (NEGATIVE)'	Julia Klopfer (b) (4)	21 Oct 2020 18:11:52

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:33

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'No (N)'	Julia Klopfer (b) (4)	21 Oct 2020 18:11:52

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:33

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered empty.	Julia Klopfer (b) (4)	21 Oct 2020 18:11:52

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:33

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered empty.	Julia Klopfer (b) (4)	21 Oct 2020 18:11:52



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Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered empty.	System	21 Oct 2020 18:11:52

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:41:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	21 Oct 2020 16:06:10

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:41:33

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered empty.	Julia Klopfer (b) (4)	21 Oct 2020 16:06:10

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:41:33

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 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered empty.	Julia Klopfer (b) (4)	21 Oct 2020 16:06:10

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:41:33

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'MRNA-1273 OR PLACEBO'	System	21 Oct 2020 16:06:10

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:41:33

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '21 Oct 2020'	Julia Klopfer (b) (4)	21 Oct 2020 16:06:10

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:41:33

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '11:59'	Julia Klopfer (b) (4)	21 Oct 2020 16:06:10

US3432627

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:41:33

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered '21 Oct 2020 11:59'	System	21 Oct 2020 16:06:10



US3432627

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:41:33

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Left Arm (LEFT ARM)'	Julia Klopfer (b) (4)	21 Oct 2020 16:06:10

US3432627

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:41:33

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'ONCE'	System	21 Oct 2020 16:06:10

US3432627

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:41:33

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'INTRAMUSCULAR'	System	21 Oct 2020 16:06:10

US3432627

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	21 Oct 2020 18:23:11

US3432627

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '21 Oct 2020'	Julia Klopfer (b) (4)	21 Oct 2020 18:23:11

US3432627

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '11:38'	Julia Klopfer (b) (4)	21 Oct 2020 18:23:11

US3432627

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:33

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered '21 Oct 2020 11:38'	System	21 Oct 2020 18:23:11

US3432627

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:41:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '21 Oct 2020'	Julia Klopfer (b) (4)	21 Oct 2020 18:23:25



US3432627

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:41:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Julia Klopfer (b) (4) (b) (4)	21 Oct 2020 18:23:25

US3432627

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:41:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	21 Oct 2020 18:23:25

US3432627

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:41:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '11:45'	Julia Klopfer (b) (4)	21 Oct 2020 18:23:25

US3432627

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:41:33

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered '21 Oct 2020 11:45'	System	21 Oct 2020 18:23:25

US3432627

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:41:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Julia Klopfer (b) (4) (b) (4)	21 Oct 2020 18:23:25

US3432627

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:41:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'No (N)'	Julia Klopfer (b) (4)	21 Oct 2020 18:23:25

US3432627

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:41:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered empty.	Julia Klopfer (b) (4)	21 Oct 2020 18:23:25

US3432627

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:41:33

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered empty.	System	21 Oct 2020 18:23:25



US3432627

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:41:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	21 Oct 2020 18:23:30

US3432627

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:41:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'I'	System	21 Oct 2020 18:23:30

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	21 Oct 2020 16:06:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-21T12:37:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '0a5b4a99-d5c9-4061-9dca-9e55e9e476ca' User entered 'Yes (Y)'	System	21 Oct 2020 16:37:21
	System	21 Oct 2020 16:37:21

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-21T12:37:07', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '0a5b4a99-d5c9-4061-9dca-9e55e9e476ca' User entered '97.5'	System	21 Oct 2020 16:37:21
	System	21 Oct 2020 16:37:21

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-21T12:37:11', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '0a5b4a99-d5c9-4061-9dca-9e55e9e476ca' User entered 'No (N)'	System	21 Oct 2020 16:37:21
	System	21 Oct 2020 16:37:21

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-21T12:37:15', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '0a5b4a99-d5c9-4061-9dca-9e55e9e476ca' User entered '21 Oct 2020 12:37'	System	21 Oct 2020 16:37:21
	System	21 Oct 2020 16:37:21

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '21 Oct 2020 12:19'	System	21 Oct 2020 16:06:10



US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '21 Oct 2020 14:49'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	21 Oct 2020 16:06:10
User entered 'Day 1, after vaccination (at home)'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-21T20:46:56', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'c0179478-cd1d-481b-858c-49d80c575c6b' User entered 'Yes (Y)'	System	22 Oct 2020 00:48:58
	System	22 Oct 2020 00:48:58

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-21T20:48:47', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'c0179478-cd1d-481b-858c-49d80c575c6b' User entered '96.9'	System	22 Oct 2020 00:48:58
	System	22 Oct 2020 00:48:58

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-21T20:48:51', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'c0179478-cd1d-481b-858c-49d80c575c6b' User entered 'No (N)'	System	22 Oct 2020 00:48:58
	System	22 Oct 2020 00:48:58

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-21T20:48:55', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'c0179478-cd1d-481b-858c-49d80c575c6b' User entered '21 Oct 2020 20:48'	System	22 Oct 2020 00:48:58
	System	22 Oct 2020 00:48:58

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '21 Oct 2020 15:44'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '22 Oct 2020 11:59'	System	21 Oct 2020 16:06:10



US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	21 Oct 2020 16:06:10
User entered 'Day 2'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:41:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:41:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:41:33

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:41:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 16:06:10



US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	21 Oct 2020 16:06:10
User entered 'Day 3'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:41:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-23T18:53:10', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'a159ee0c-119c-4148-a3d4-7dd0a22b4e58' User entered 'Yes (Y)'	System	23 Oct 2020 22:53:53
	System	23 Oct 2020 22:53:53

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:41:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-23T18:53:45', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'a159ee0c-119c-4148-a3d4-7dd0a22b4e58' User entered '98.4'	System	23 Oct 2020 22:53:53
	System	23 Oct 2020 22:53:53

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-23T18:53:48', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'a159ee0c-119c-4148-a3d4-7dd0a22b4e58'	System	23 Oct 2020 22:53:53
User entered 'No (N)'	System	23 Oct 2020 22:53:53

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:41:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-23T18:53:51', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'a159ee0c-119c-4148-a3d4-7dd0a22b4e58' User entered '23 Oct 2020 18:53'	System	23 Oct 2020 22:53:53
	System	23 Oct 2020 22:53:53

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 16:06:10



US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	21 Oct 2020 16:06:10
User entered 'Day 4'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:41:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-25T11:20:57', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '2c8be56f-a6ed-42eb-97e9-1923428346cc' User entered 'Yes (Y)'	System	25 Oct 2020 15:22:06
	System	25 Oct 2020 15:22:06

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:41:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-25T11:21:56', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '2c8be56f-a6ed-42eb-97e9-1923428346cc' User entered '96.3'	System	25 Oct 2020 15:22:06
	System	25 Oct 2020 15:22:06

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-25T11:21:59', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '2c8be56f-a6ed-42eb-97e9-1923428346cc' User entered 'No (N)'	System	25 Oct 2020 15:22:06
	System	25 Oct 2020 15:22:06

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:41:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-25T11:22:01', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '2c8be56f-a6ed-42eb-97e9-1923428346cc' User entered '25 Oct 2020 11:22'	System	25 Oct 2020 15:22:06
	System	25 Oct 2020 15:22:06

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '24 Oct 2020 12:00'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '25 Oct 2020 11:59'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	21 Oct 2020 16:06:10
User entered 'Day 5'	System	21 Oct 2020 16:06:10



US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:41:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:41:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:41:33

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:41:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '25 Oct 2020 12:00'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '26 Oct 2020 11:59'	System	21 Oct 2020 16:06:10



US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	21 Oct 2020 16:06:10
User entered 'Day 6'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:41:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-26T19:49:37', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '1b8d0d70-b8f6-48ff-8d2e-5fbefa2614d1' User entered 'Yes (Y)'	System	26 Oct 2020 23:49:49
	System	26 Oct 2020 23:49:49

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:41:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-26T19:49:41', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '1b8d0d70-b8f6-48ff-8d2e-5fbefa2614d1' User entered '98.6'	System	26 Oct 2020 23:49:49
	System	26 Oct 2020 23:49:49

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-26T19:49:43', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '1b8d0d70-b8f6-48ff-8d2e-5fbefa2614d1' User entered 'No (N)'	System	26 Oct 2020 23:49:49
	System	26 Oct 2020 23:49:49

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:41:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-26T19:49:45', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '1b8d0d70-b8f6-48ff-8d2e-5fbefa2614d1' User entered '26 Oct 2020 19:49'	System	26 Oct 2020 23:49:49
	System	26 Oct 2020 23:49:49

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '26 Oct 2020 12:00'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '27 Oct 2020 11:59'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	21 Oct 2020 16:06:10
User entered 'Day 7'	System	21 Oct 2020 16:06:10



US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:41:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:41:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:41:33

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:41:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '27 Oct 2020 12:00'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '28 Oct 2020 11:59'	System	21 Oct 2020 16:06:10



US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	21 Oct 2020 16:06:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-21T12:37:30', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '13d1f40b-5e0a-4fdd-ae9b-61390a9a3c21' User entered 'None (1)'	System	21 Oct 2020 16:38:58
	System	21 Oct 2020 16:38:58

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-21T12:37:37', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '13d1f40b-5e0a-4fdd-ae9b-61390a9a3c21' User entered 'Yes (Y)'	System	21 Oct 2020 16:38:58
	System	21 Oct 2020 16:38:58

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-21T12:38:39', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '13d1f40b-5e0a-4fdd-ae9b-61390a9a3c21' User entered '80'	System	21 Oct 2020 16:38:58
	System	21 Oct 2020 16:38:58

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-21T12:38:42', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '13d1f40b-5e0a-4fdd-ae9b-61390a9a3c21' User entered 'No (N)'	System	21 Oct 2020 16:38:58
	System	21 Oct 2020 16:38:58

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-21T12:38:49', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '13d1f40b-5e0a-4fdd-ae9b-61390a9a3c21' User entered 'None (1)'	System	21 Oct 2020 16:38:58
	System	21 Oct 2020 16:38:58

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-21T12:38:52', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '13d1f40b-5e0a-4fdd-ae9b-61390a9a3c21' User entered '21 Oct 2020 12:38'	System	21 Oct 2020 16:38:58
	System	21 Oct 2020 16:38:58

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '21 Oct 2020 12:19'	System	21 Oct 2020 16:06:10



US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '21 Oct 2020 14:49'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	21 Oct 2020 16:06:10
User entered 'Day 1, after vaccination (at home)'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-21T20:49:13', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'c5d67792-de66-4825-8837-f4e01ff5c009'	System	22 Oct 2020 00:50:37
User entered 'Does not interfere with activity (2)'	System	22 Oct 2020 00:50:37

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-21T20:49:18', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'c5d67792-de66-4825-8837-f4e01ff5c009' User entered 'No (N)'	System	22 Oct 2020 00:50:37
	System	22 Oct 2020 00:50:37

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-21T20:49:30', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'c5d67792-de66-4825-8837-f4e01ff5c009' User entered 'Yes (Y)'	System	22 Oct 2020 00:50:37
	System	22 Oct 2020 00:50:37

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-21T20:50:24', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'c5d67792-de66-4825-8837-f4e01ff5c009' User entered '2'	System	22 Oct 2020 00:50:37
	System	22 Oct 2020 00:50:37

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-21T20:50:29', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'c5d67792-de66-4825-8837-f4e01ff5c009'	System	22 Oct 2020 00:50:37
User entered 'None (1)'	System	22 Oct 2020 00:50:37

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-21T20:50:33', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'c5d67792-de66-4825-8837-f4e01ff5c009' User entered '21 Oct 2020 20:50'	System	22 Oct 2020 00:50:37
	System	22 Oct 2020 00:50:37



US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '21 Oct 2020 15:44'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '22 Oct 2020 11:59'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	21 Oct 2020 16:06:10
User entered 'Day 2'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:41:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49



US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:41:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	21 Oct 2020 16:06:10
User entered 'Day 3'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-23T18:51:13', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '1629ecb1-47de-4acd-8e5e-0d11c458d47a' User entered 'None (1)'	System	23 Oct 2020 22:51:24
	System	23 Oct 2020 22:51:24

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:41:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-23T18:51:16', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '1629ecb1-47de-4acd-8e5e-0d11c458d47a' User entered 'No (N)'	System	23 Oct 2020 22:51:24
	System	23 Oct 2020 22:51:24

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-23T18:51:18', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '1629ecb1-47de-4acd-8e5e-0d11c458d47a' User entered 'No (N)'	System	23 Oct 2020 22:51:24
	System	23 Oct 2020 22:51:24



US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-23T18:51:19', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '1629ecb1-47de-4acd-8e5e-0d11c458d47a' User entered 'None (1)'	System	23 Oct 2020 22:51:24
	System	23 Oct 2020 22:51:24

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:41:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-23T18:51:22', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '1629ecb1-47de-4acd-8e5e-0d11c458d47a' User entered '23 Oct 2020 18:51'	System	23 Oct 2020 22:51:24
	System	23 Oct 2020 22:51:24

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	21 Oct 2020 16:06:10
User entered 'Day 4'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-25T11:20:24', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '9d656b98-dd36-4cdf-b50b-483b86c73acc'	System	25 Oct 2020 15:20:37
User entered 'None (1)'	System	25 Oct 2020 15:20:37

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:41:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-25T11:20:26', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '9d656b98-dd36-4cdf-b50b-483b86c73acc' User entered 'No (N)'	System	25 Oct 2020 15:20:37
	System	25 Oct 2020 15:20:37

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-25T11:20:28', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '9d656b98-dd36-4cdf-b50b-483b86c73acc' User entered 'No (N)'	System	25 Oct 2020 15:20:37
	System	25 Oct 2020 15:20:37



US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-25T11:20:30', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '9d656b98-dd36-4cdf-b50b-483b86c73acc'	System	25 Oct 2020 15:20:37
User entered 'None (1)'	System	25 Oct 2020 15:20:37

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:41:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-25T11:20:33', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '9d656b98-dd36-4cdf-b50b-483b86c73acc' User entered '25 Oct 2020 11:20'	System	25 Oct 2020 15:20:37
	System	25 Oct 2020 15:20:37

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '24 Oct 2020 12:00'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '25 Oct 2020 11:59'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	21 Oct 2020 16:06:10
User entered 'Day 5'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49



US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:41:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '25 Oct 2020 12:00'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '26 Oct 2020 11:59'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	21 Oct 2020 16:06:10
User entered 'Day 6'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-26T19:48:55', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'c3c55f15-f18c-4ec9-9ee3-bd810a5d9ab9'	System	26 Oct 2020 23:49:04
User entered 'None (1)'	System	26 Oct 2020 23:49:04



US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:41:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-26T19:48:57', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'c3c55f15-f18c-4ec9-9ee3-bd810a5d9ab9' User entered 'No (N)'	System	26 Oct 2020 23:49:04
	System	26 Oct 2020 23:49:04

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-26T19:48:59', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'c3c55f15-f18c-4ec9-9ee3-bd810a5d9ab9' User entered 'No (N)'	System	26 Oct 2020 23:49:04
	System	26 Oct 2020 23:49:04

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-26T19:49:01', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'c3c55f15-f18c-4ec9-9ee3-bd810a5d9ab9'	System	26 Oct 2020 23:49:04
User entered 'None (1)'	System	26 Oct 2020 23:49:04

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:41:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-26T19:49:03', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'c3c55f15-f18c-4ec9-9ee3-bd810a5d9ab9' User entered '26 Oct 2020 19:49'	System	26 Oct 2020 23:49:04
	System	26 Oct 2020 23:49:04

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '26 Oct 2020 12:00'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '27 Oct 2020 11:59'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	21 Oct 2020 16:06:10
User entered 'Day 7'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49



US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:41:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '27 Oct 2020 12:00'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '28 Oct 2020 11:59'	System	21 Oct 2020 16:06:10



US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	21 Oct 2020 16:06:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-21T12:38:58', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'e9df2749-6f6d-44e1-9f50-70e9b9043b4f' User entered 'None (0)'	System	21 Oct 2020 16:39:27
	System	21 Oct 2020 16:39:27

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-21T12:39:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'e9df2749-6f6d-44e1-9f50-70e9b9043b4f' User entered 'None (0)'	System	21 Oct 2020 16:39:27
	System	21 Oct 2020 16:39:27

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-21T12:39:04', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'e9df2749-6f6d-44e1-9f50-70e9b9043b4f' User entered 'None (0)'	System	21 Oct 2020 16:39:27
	System	21 Oct 2020 16:39:27

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-21T12:39:07', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'e9df2749-6f6d-44e1-9f50-70e9b9043b4f' User entered 'None (0)'	System	21 Oct 2020 16:39:27
	System	21 Oct 2020 16:39:27

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-21T12:39:09', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'e9df2749-6f6d-44e1-9f50-70e9b9043b4f' User entered 'None (0)'	System	21 Oct 2020 16:39:27
	System	21 Oct 2020 16:39:27

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-21T12:39:11', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'e9df2749-6f6d-44e1-9f50-70e9b9043b4f' User entered 'None (0)'	System	21 Oct 2020 16:39:27
	System	21 Oct 2020 16:39:27

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-21T12:39:21', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'e9df2749-6f6d-44e1-9f50-70e9b9043b4f' User entered 'No (N)'	System	21 Oct 2020 16:39:27
	System	21 Oct 2020 16:39:27



US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-21T12:39:24', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'e9df2749-6f6d-44e1-9f50-70e9b9043b4f' User entered '21 Oct 2020 12:39'	System	21 Oct 2020 16:39:27
	System	21 Oct 2020 16:39:27

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '21 Oct 2020 12:19'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '21 Oct 2020 14:49'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	21 Oct 2020 16:06:10
User entered 'Day 1, after vaccination (at home)'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-21T20:50:38', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'd029ea2e-195a-4355-be8a-1175d65c0c73' User entered 'None (0)'	System	22 Oct 2020 00:50:56
	System	22 Oct 2020 00:50:56

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-21T20:50:41', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'd029ea2e-195a-4355-be8a-1175d65c0c73' User entered 'None (0)'	System	22 Oct 2020 00:50:56
	System	22 Oct 2020 00:50:56

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-21T20:50:43', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'd029ea2e-195a-4355-be8a-1175d65c0c73' User entered 'None (0)'	System	22 Oct 2020 00:50:56
	System	22 Oct 2020 00:50:56

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-21T20:50:45', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'd029ea2e-195a-4355-be8a-1175d65c0c73' User entered 'None (0)'	System	22 Oct 2020 00:50:56
	System	22 Oct 2020 00:50:56



US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-21T20:50:47', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'd029ea2e-195a-4355-be8a-1175d65c0c73' User entered 'None (0)'	System	22 Oct 2020 00:50:56
	System	22 Oct 2020 00:50:56

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-21T20:50:49', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'd029ea2e-195a-4355-be8a-1175d65c0c73' User entered 'None (0)'	System	22 Oct 2020 00:50:56
	System	22 Oct 2020 00:50:56

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-21T20:50:52', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'd029ea2e-195a-4355-be8a-1175d65c0c73'	System	22 Oct 2020 00:50:56
User entered 'No (N)'	System	22 Oct 2020 00:50:56

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-21T20:50:54', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'd029ea2e-195a-4355-be8a-1175d65c0c73' User entered '21 Oct 2020 20:50'	System	22 Oct 2020 00:50:56
	System	22 Oct 2020 00:50:56

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '21 Oct 2020 15:44'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '22 Oct 2020 11:59'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	21 Oct 2020 16:06:10
User entered 'Day 2'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49



US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 16:06:10



US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	21 Oct 2020 16:06:10
User entered 'Day 3'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-23T18:53:54', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '8718ef89-c6d4-4669-83ec-1d8f12f53b17' User entered 'None (0)'	System	23 Oct 2020 22:54:10
	System	23 Oct 2020 22:54:10

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-23T18:53:56', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '8718ef89-c6d4-4669-83ec-1d8f12f53b17' User entered 'None (0)'	System	23 Oct 2020 22:54:10
	System	23 Oct 2020 22:54:10

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-23T18:53:58', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '8718ef89-c6d4-4669-83ec-1d8f12f53b17' User entered 'None (0)'	System	23 Oct 2020 22:54:10
	System	23 Oct 2020 22:54:10

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-23T18:53:59', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '8718ef89-c6d4-4669-83ec-1d8f12f53b17' User entered 'None (0)'	System	23 Oct 2020 22:54:10
	System	23 Oct 2020 22:54:10

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-23T18:54:01', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '8718ef89-c6d4-4669-83ec-1d8f12f53b17' User entered 'None (0)'	System	23 Oct 2020 22:54:10
	System	23 Oct 2020 22:54:10

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-23T18:54:02', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '8718ef89-c6d4-4669-83ec-1d8f12f53b17' User entered 'None (0)'	System	23 Oct 2020 22:54:10
	System	23 Oct 2020 22:54:10



US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-23T18:54:04', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '8718ef89-c6d4-4669-83ec-1d8f12f53b17'	System	23 Oct 2020 22:54:10
User entered 'No (N)'	System	23 Oct 2020 22:54:10

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-23T18:54:07', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '8718ef89-c6d4-4669-83ec-1d8f12f53b17' User entered '23 Oct 2020 18:54'	System	23 Oct 2020 22:54:10
	System	23 Oct 2020 22:54:10

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '23 Oct 2020 12:00'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '24 Oct 2020 11:59'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	21 Oct 2020 16:06:10
User entered 'Day 4'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-25T11:20:36', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '91b49c59-e3cf-41a9-8515-17c6b379a48f' User entered 'None (0)'	System	25 Oct 2020 15:20:50
	System	25 Oct 2020 15:20:50

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-25T11:20:38', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '91b49c59-e3cf-41a9-8515-17c6b379a48f' User entered 'None (0)'	System	25 Oct 2020 15:20:50
	System	25 Oct 2020 15:20:50

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-25T11:20:39', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '91b49c59-e3cf-41a9-8515-17c6b379a48f' User entered 'None (0)'	System	25 Oct 2020 15:20:50
	System	25 Oct 2020 15:20:50



US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-25T11:20:41', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '91b49c59-e3cf-41a9-8515-17c6b379a48f' User entered 'None (0)'	System	25 Oct 2020 15:20:50
	System	25 Oct 2020 15:20:50

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-25T11:20:42', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '91b49c59-e3cf-41a9-8515-17c6b379a48f' User entered 'None (0)'	System	25 Oct 2020 15:20:50
	System	25 Oct 2020 15:20:50

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-25T11:20:44', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '91b49c59-e3cf-41a9-8515-17c6b379a48f' User entered 'None (0)'	System	25 Oct 2020 15:20:50
	System	25 Oct 2020 15:20:50

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-25T11:20:46', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '91b49c59-e3cf-41a9-8515-17c6b379a48f' User entered 'No (N)'	System	25 Oct 2020 15:20:50
	System	25 Oct 2020 15:20:50

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-25T11:20:48', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '91b49c59-e3cf-41a9-8515-17c6b379a48f' User entered '25 Oct 2020 11:20'	System	25 Oct 2020 15:20:50
	System	25 Oct 2020 15:20:50

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '24 Oct 2020 12:00'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '25 Oct 2020 11:59'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	21 Oct 2020 16:06:10
User entered 'Day 5'	System	21 Oct 2020 16:06:10



US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49



US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '25 Oct 2020 12:00'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '26 Oct 2020 11:59'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	21 Oct 2020 16:06:10
User entered 'Day 6'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-26T19:49:14', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '4f7f83ff-ff90-4ab1-9e66-cbdd0fa5c779'	System	26 Oct 2020 23:49:34
User entered 'No interference with activity (1)'	System	26 Oct 2020 23:49:34

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-26T19:49:17', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '4f7f83ff-ff90-4ab1-9e66-cbdd0fa5c779' User entered 'None (0)'	System	26 Oct 2020 23:49:34
	System	26 Oct 2020 23:49:34

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-26T19:49:19', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '4f7f83ff-ff90-4ab1-9e66-cbdd0fa5c779' User entered 'None (0)'	System	26 Oct 2020 23:49:34
	System	26 Oct 2020 23:49:34

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-26T19:49:23', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '4f7f83ff-ff90-4ab1-9e66-cbdd0fa5c779' User entered 'None (0)'	System	26 Oct 2020 23:49:34
	System	26 Oct 2020 23:49:34

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-26T19:49:25', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '4f7f83ff-ff90-4ab1-9e66-cbdd0fa5c779' User entered 'None (0)'	System	26 Oct 2020 23:49:34
	System	26 Oct 2020 23:49:34



US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-26T19:49:26', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '4f7f83ff-ff90-4ab1-9e66-cbdd0fa5c779' User entered 'None (0)'	System	26 Oct 2020 23:49:34
	System	26 Oct 2020 23:49:34

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-26T19:49:29', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '4f7f83ff-ff90-4ab1-9e66-cbdd0fa5c779' User entered 'No (N)'	System	26 Oct 2020 23:49:34
	System	26 Oct 2020 23:49:34

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-10-26T19:49:32', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '4f7f83ff-ff90-4ab1-9e66-cbdd0fa5c779' User entered '26 Oct 2020 19:49'	System	26 Oct 2020 23:49:34
	System	26 Oct 2020 23:49:34

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '26 Oct 2020 12:00'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '27 Oct 2020 11:59'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	21 Oct 2020 16:06:10
User entered 'Day 7'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49



US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '27 Oct 2020 12:00'	System	21 Oct 2020 16:06:10

US3432627

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '28 Oct 2020 11:59'	System	21 Oct 2020 16:06:10



US3432627

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	26 Oct 2020 23:49:34
User entered 'Day 8'	System	26 Oct 2020 23:49:34

US3432627

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 17:41:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '28 Oct 2020 12:00'	System	26 Oct 2020 23:49:34

US3432627

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '29 Oct 2020 11:59'	System	26 Oct 2020 23:49:34

US3432627

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	26 Oct 2020 23:49:34
User entered 'Day 8'	System	26 Oct 2020 23:49:34

US3432627

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49

US3432627

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:41:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49



US3432627

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '28 Oct 2020 12:00'	System	26 Oct 2020 23:49:34

US3432627

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '29 Oct 2020 11:59'	System	26 Oct 2020 23:49:34

US3432627

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	28 Oct 2020 21:33:41

US3432627

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '28 Oct 2020'	Julia Klopfer (b) (4)	28 Oct 2020 21:33:41

US3432627

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Contact Made (CONTACT MADE)'	Julia Klopfer (b) (4)	28 Oct 2020 21:33:41

US3432627

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered empty.	Julia Klopfer (b) (4)	28 Oct 2020 21:33:41

US3432627

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 13:43:56

US3432627

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'I'	System	04 Nov 2020 13:43:56



US3432627

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 13:46:18

US3432627

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered '4 Nov 2020'	(b) (4), (b) (6)	04 Nov 2020 13:46:18

US3432627

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	04 Nov 2020 13:46:18

US3432627

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 13:46:18

US3432627

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Nov 2020 13:46:36

US3432627

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'I'	System	04 Nov 2020 13:46:36

US3432627

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 14:12:31

US3432627

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered '11 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 14:12:31



US3432627

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Nov 2020 14:12:31

US3432627

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 14:12:31

US3432627

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 14:12:35

US3432627

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'I'	System	11 Nov 2020 14:12:35

US3432627

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	18 Nov 2020 18:29:07

US3432627

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:33

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '18 Nov 2020'	Kathleen Garvey (b) (4)	18 Nov 2020 18:29:07

US3432627

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:33

[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 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Clinic (Clinic)'	Kathleen Garvey (b) (4)	18 Nov 2020 18:29:07

US3432627

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'VISIT2'	System	18 Nov 2020 18:29:07



US3432627

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User accepted default value 'Pre-Dose (PREDOSE)'	Kathleen Garvey (b) (4) (b) (4)	18 Nov 2020 18:55:08

US3432627

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	18 Nov 2020 18:55:08

US3432627

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '18 Nov 2020'	Kathleen Garvey (b) (4)	18 Nov 2020 18:55:08

US3432627

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:33

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '12:50'	Kathleen Garvey (b) (4)	18 Nov 2020 18:55:08

US3432627

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered '18 Nov 2020 12:50'	System	18 Nov 2020 18:55:08

US3432627

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '98.7' F	Kathleen Garvey (b) (4)	18 Nov 2020 18:55:08

US3432627

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Oral (Oral)'	Kathleen Garvey (b) (4)	18 Nov 2020 18:55:08

US3432627

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered empty.	Kathleen Garvey (b) (4)	18 Nov 2020 18:55:08



US3432627

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '100'	Kathleen Garvey (b) (4)	18 Nov 2020 18:55:08

US3432627

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'bpm'	System	18 Nov 2020 18:55:08

US3432627

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '16'	Kathleen Garvey (b) (4)	18 Nov 2020 18:55:08

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'breaths/min'	System	18 Nov 2020 18:55:08

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '122'	Kathleen Garvey (b) (4)	18 Nov 2020 18:55:08

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'mmHg'	System	18 Nov 2020 18:55:08

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '67'	Kathleen Garvey (b) (4)	18 Nov 2020 18:55:08

US3432627

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:41:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'mmHg'	System	18 Nov 2020 18:55:08



US3432627

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User accepted default value 'Post-Dose (POSTDOSE)'	Kathleen Garvey (b) (4) (b) (4)	18 Nov 2020 18:55:08

US3432627

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:33

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 19:59:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Nov 2020 19:59:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Kathleen Garvey (b) (4)	18 Nov 2020 19:59:44
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 18:55:08
User entered empty.	Kathleen Garvey (b) (4)	18 Nov 2020 18:55:08

US3432627

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '18 Nov 2020' reason for change: Data Entry Error	Kathleen Garvey (b) (4)	18 Nov 2020 19:59:44
User entered empty.	(b) (4)	
	Kathleen Garvey (b) (4)	18 Nov 2020 18:55:08
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:33

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '14:50' reason for change: Data Entry Error	Kathleen Garvey (b) (4)	18 Nov 2020 19:59:44
User entered empty.	Kathleen Garvey (b) (4)	18 Nov 2020 18:55:08

US3432627

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered '18 Nov 2020 14:50'	System	18 Nov 2020 19:59:44
User entered empty.	System	18 Nov 2020 18:55:08

US3432627

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '98.3' F reason for change: Data Entry Error	Kathleen Garvey (b) (4)	18 Nov 2020 19:59:44
User entered empty.	Kathleen Garvey (b) (4)	18 Nov 2020 18:55:08

US3432627

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Oral (Oral)' reason for change: Data Entry Error	Kathleen Garvey (b) (4)	18 Nov 2020 19:59:44
User entered empty.	Kathleen Garvey (b) (4)	18 Nov 2020 18:55:08

US3432627

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered empty.	Kathleen Garvey (b) (4)	18 Nov 2020 18:55:08



US3432627

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '88' reason for change: Data Entry Error	Kathleen Garvey (b) (4)	18 Nov 2020 19:59:44
User entered empty.	Kathleen Garvey (b) (4)	18 Nov 2020 18:55:08

US3432627

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'bpm'	System	18 Nov 2020 19:59:44
User entered empty.	System	18 Nov 2020 18:55:08

US3432627

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '14' reason for change: Data Entry Error	Kathleen Garvey (b) (4)	18 Nov 2020 19:59:44
User entered empty.	Kathleen Garvey (b) (4)	18 Nov 2020 18:55:08

US3432627

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'breaths/min'	System	18 Nov 2020 19:59:44
User entered empty.	System	18 Nov 2020 18:55:08

US3432627

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '125' reason for change: Data Entry Error	Kathleen Garvey (b) (4)	18 Nov 2020 19:59:44
User entered empty.	Kathleen Garvey (b) (4)	18 Nov 2020 18:55:08

US3432627

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'mmHg'	System	18 Nov 2020 19:59:44
User entered empty.	System	18 Nov 2020 18:55:08

US3432627

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '79' reason for change: Data Entry Error	Kathleen Garvey (b) (4)	18 Nov 2020 19:59:44
User entered empty.	Kathleen Garvey (b) (4)	18 Nov 2020 18:55:08

US3432627

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:41:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'mmHg'	System	18 Nov 2020 19:59:44
User entered empty.	System	18 Nov 2020 18:55:08



US3432627

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	18 Nov 2020 18:51:55

US3432627

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '18 Nov 2020'	Kathleen Garvey (b) (4)	18 Nov 2020 18:51:55

US3432627

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:33

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	18 Nov 2020 18:29:24

US3432627

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:33

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '18 Nov 2020'	Kathleen Garvey (b) (4)	18 Nov 2020 18:29:24

US3432627

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:33

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Urine (URINE)'	Kathleen Garvey (b) (4)	18 Nov 2020 18:29:24

US3432627

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:33

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Negative (NEGATIVE)'	Kathleen Garvey (b) (4)	18 Nov 2020 18:29:24

US3432627

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:33

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'No (N)'	Kathleen Garvey (b) (4)	18 Nov 2020 18:29:24

US3432627

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:33

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered empty.	Kathleen Garvey (b) (4)	18 Nov 2020 18:29:24



US3432627

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:33

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered empty.	Kathleen Garvey (b) (4)	18 Nov 2020 18:29:24

US3432627

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:41:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered empty.	System	18 Nov 2020 18:29:24

US3432627

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	18 Nov 2020 19:26:05

US3432627

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:33

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered empty.	Kathleen Garvey (b) (4)	18 Nov 2020 19:26:05

US3432627

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:33

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 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered empty.	Kathleen Garvey (b) (4)	18 Nov 2020 19:26:05

US3432627

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:33

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'MRNA-1273 OR PLACEBO'	System	18 Nov 2020 19:26:05

US3432627

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:33

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '18 Nov 2020'	Kathleen Garvey (b) (4)	18 Nov 2020 19:26:05

US3432627

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:33

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '14:17'	Kathleen Garvey (b) (4)	18 Nov 2020 19:26:05



US3432627

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:33

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered '18 Nov 2020 14:17'	System	18 Nov 2020 19:26:05

US3432627

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:33

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Left Arm (LEFT ARM)'	Kathleen Garvey (b) (4)	18 Nov 2020 19:26:05

US3432627

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:33

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'ONCE'	System	18 Nov 2020 19:26:05

US3432627

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:41:33

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'INTRAMUSCULAR'	System	18 Nov 2020 19:26:05

US3432627

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	18 Nov 2020 18:51:42

US3432627

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:33

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '18 Nov 2020'	Kathleen Garvey (b) (4)	18 Nov 2020 18:51:42

US3432627

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '13:40'	Kathleen Garvey (b) (4)	18 Nov 2020 18:51:42

US3432627

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered '18 Nov 2020 13:40'	System	18 Nov 2020 18:51:42



US3432627

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:41:33

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '18 Nov 2020'	Kathleen Garvey (b) (4)	18 Nov 2020 19:12:17

US3432627

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:41:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Kathleen Garvey (b) (4) (b) (4)	18 Nov 2020 19:12:17

US3432627

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:41:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	18 Nov 2020 19:12:17

US3432627

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:41:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '14:05'	Kathleen Garvey (b) (4)	18 Nov 2020 19:12:17

**US3432627**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:41:33**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered '18 Nov 2020 14:05'	System	18 Nov 2020 19:12:17

US3432627

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:41:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Kathleen Garvey (b) (4) (b) (4)	18 Nov 2020 19:12:17

US3432627

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:41:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'No (N)'	Kathleen Garvey (b) (4)	18 Nov 2020 19:12:17

US3432627

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:41:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered empty.	Kathleen Garvey (b) (4)	18 Nov 2020 19:12:17



US3432627

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:41:33

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered empty.	System	18 Nov 2020 19:12:17

US3432627

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	18 Nov 2020 19:59:53

US3432627

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'I'	System	18 Nov 2020 19:59:53

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	18 Nov 2020 19:26:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-18T14:51:17', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'f35c8559-05b0-485b-93f8-9074f157d3e2' User entered 'Yes (Y)'	System	18 Nov 2020 19:51:33
	System	18 Nov 2020 19:51:33

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-18T14:51:22', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'f35c8559-05b0-485b-93f8-9074f157d3e2' User entered '98.3'	System	18 Nov 2020 19:51:33
	System	18 Nov 2020 19:51:33

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-18T14:51:25', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'f35c8559-05b0-485b-93f8-9074f157d3e2'	System	18 Nov 2020 19:51:33
User entered 'No (N)'	System	18 Nov 2020 19:51:33

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-18T14:51:30', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'f35c8559-05b0-485b-93f8-9074f157d3e2' User entered '18 Nov 2020 14:51'	System	18 Nov 2020 19:51:33
	System	18 Nov 2020 19:51:33



US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '18 Nov 2020 14:37'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '18 Nov 2020 17:07'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	18 Nov 2020 19:26:05
User entered 'Day 1, after vaccination (at home)'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-18T18:45:46', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '9a189def-51ff-402a-a660-e6e41c9c6224' User entered 'No (N)'	System	18 Nov 2020 23:45:56
	System	18 Nov 2020 23:45:56

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-18T18:45:50', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '9a189def-51ff-402a-a660-e6e41c9c6224' User entered 'No (N)'	System	18 Nov 2020 23:45:56
	System	18 Nov 2020 23:45:56

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-18T18:45:52', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '9a189def-51ff-402a-a660-e6e41c9c6224' User entered '18 Nov 2020 18:45'	System	18 Nov 2020 23:45:56
	System	18 Nov 2020 23:45:56

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '18 Nov 2020 18:02'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '19 Nov 2020 11:59'	System	18 Nov 2020 19:26:05



US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	18 Nov 2020 19:26:05
User entered 'Day 2'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:41:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-19T14:28:04', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'ebf46b36-1183-4b2a-8f07-dc48bae52461' User entered 'Yes (Y)'	System	19 Nov 2020 19:28:22
	System	19 Nov 2020 19:28:22

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:41:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-19T14:28:08', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'ebf46b36-1183-4b2a-8f07-dc48bae52461' User entered '99.6'	System	19 Nov 2020 19:28:22
	System	19 Nov 2020 19:28:22

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-19T14:28:12', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'ebf46b36-1183-4b2a-8f07-dc48bae52461' User entered 'Yes (Y)'	System	19 Nov 2020 19:28:22
	System	19 Nov 2020 19:28:22

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
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 'Pt. contacted and tylenol added to conmeds' (Site from System).	(b) (4), (b) (6)	10 Dec 2020 07:08:49
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). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-19T14:28:16', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'ebf46b36-1183-4b2a-8f07-dc48bae52461' User entered '1'	Phoebe Cunningham (b) (4)	03 Dec 2020 19:32:54
	System	19 Nov 2020 19:28:22
	System	19 Nov 2020 19:28:22
	System	19 Nov 2020 19:28:22

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:41:33

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-19T14:28:16', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'ebf46b36-1183-4b2a-8f07-dc48bae52461' User entered '0'	System	19 Nov 2020 19:28:22
	System	19 Nov 2020 19:28:22

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:41:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-19T14:28:19', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'ebf46b36-1183-4b2a-8f07-dc48bae52461' User entered '19 Nov 2020 14:28'	System	19 Nov 2020 19:28:22
	System	19 Nov 2020 19:28:22

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '19 Nov 2020 12:00'	System	18 Nov 2020 19:26:05



US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '20 Nov 2020 11:59'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	18 Nov 2020 19:26:05
User entered 'Day 3'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:41:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:41:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:41:33

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:41:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49



US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '20 Nov 2020 12:00'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '21 Nov 2020 11:59'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	18 Nov 2020 19:26:05
User entered 'Day 4'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:41:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:41:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:41:33

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49



US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:41:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '21 Nov 2020 12:00'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '22 Nov 2020 11:59'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	18 Nov 2020 19:26:05
User entered 'Day 5'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:41:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:41:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49



US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:41:33

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:41:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '22 Nov 2020 12:00'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '23 Nov 2020 11:59'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	18 Nov 2020 19:26:05
User entered 'Day 6'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:41:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:41:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49



US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:41:33

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:41:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '23 Nov 2020 12:00'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '24 Nov 2020 11:59'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	18 Nov 2020 19:26:05
User entered 'Day 7'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:41:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:41:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49



US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:41:33

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:41:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '24 Nov 2020 12:00'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '25 Nov 2020 11:59'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	18 Nov 2020 19:26:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-18T14:51:34', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'faac9ecd-36be-4440-924b-f6f77aab0d31'	System	18 Nov 2020 19:51:46
User entered 'None (1)'	System	18 Nov 2020 19:51:46



US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-18T14:51:36', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'faac9ecd-36be-4440-924b-f6f77aab0d31' User entered 'No (N)'	System	18 Nov 2020 19:51:46
	System	18 Nov 2020 19:51:46

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-18T14:51:38', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'faac9ecd-36be-4440-924b-f6f77aab0d31' User entered 'No (N)'	System	18 Nov 2020 19:51:46
	System	18 Nov 2020 19:51:46

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-18T14:51:41', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'faac9ecd-36be-4440-924b-f6f77aab0d31' User entered 'None (1)'	System	18 Nov 2020 19:51:46
	System	18 Nov 2020 19:51:46

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-18T14:51:43', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'faac9ecd-36be-4440-924b-f6f77aab0d31' User entered '18 Nov 2020 14:51'	System	18 Nov 2020 19:51:46
	System	18 Nov 2020 19:51:46

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '18 Nov 2020 14:37'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '18 Nov 2020 17:07'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	18 Nov 2020 19:26:05
User entered 'Day 1, after vaccination (at home)'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-18T19:00:45', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '369778f5-b4fa-4586-b7b2-3e4b2c708157'	System	19 Nov 2020 00:01:28
User entered 'Does not interfere with activity (2)'	System	19 Nov 2020 00:01:28



US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-18T19:00:47', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '369778f5-b4fa-4586-b7b2-3e4b2c708157' User entered 'No (N)'	System	19 Nov 2020 00:01:28
	System	19 Nov 2020 00:01:28

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-18T19:01:11', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '369778f5-b4fa-4586-b7b2-3e4b2c708157' User entered 'No (N)'	System	19 Nov 2020 00:01:28
	System	19 Nov 2020 00:01:28

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-18T19:01:15', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '369778f5-b4fa-4586-b7b2-3e4b2c708157'	System	19 Nov 2020 00:01:28
User entered 'None (1)'	System	19 Nov 2020 00:01:28

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-18T19:01:27', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '369778f5-b4fa-4586-b7b2-3e4b2c708157' User entered '18 Nov 2020 19:01'	System	19 Nov 2020 00:01:28
	System	19 Nov 2020 00:01:28

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '18 Nov 2020 18:02'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '19 Nov 2020 11:59'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	18 Nov 2020 19:26:05
User entered 'Day 2'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-19T14:28:24', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '46860472-39b7-4df6-94c7-da4470402151'	System	19 Nov 2020 19:28:42
User entered 'Does not interfere with activity (2)'	System	19 Nov 2020 19:28:42



US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:41:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-19T14:28:28', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '46860472-39b7-4df6-94c7-da4470402151' User entered 'No (N)'	System	19 Nov 2020 19:28:42
	System	19 Nov 2020 19:28:42

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-19T14:28:31', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '46860472-39b7-4df6-94c7-da4470402151' User entered 'No (N)'	System	19 Nov 2020 19:28:42
	System	19 Nov 2020 19:28:42

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-19T14:28:33', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '46860472-39b7-4df6-94c7-da4470402151' User entered 'None (1)'	System	19 Nov 2020 19:28:42
	System	19 Nov 2020 19:28:42

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:41:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-19T14:28:36', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '46860472-39b7-4df6-94c7-da4470402151' User entered '19 Nov 2020 14:28'	System	19 Nov 2020 19:28:42
	System	19 Nov 2020 19:28:42

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '19 Nov 2020 12:00'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '20 Nov 2020 11:59'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	18 Nov 2020 19:26:05
User entered 'Day 3'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49



US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:41:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:41:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '20 Nov 2020 12:00'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '21 Nov 2020 11:59'	System	18 Nov 2020 19:26:05



US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	18 Nov 2020 19:26:05
User entered 'Day 4'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:41:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:41:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49



US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '21 Nov 2020 12:00'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '22 Nov 2020 11:59'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	18 Nov 2020 19:26:05
User entered 'Day 5'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:41:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49



US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:41:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '22 Nov 2020 12:00'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '23 Nov 2020 11:59'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	18 Nov 2020 19:26:05
User entered 'Day 6'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:41:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49



US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:41:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '23 Nov 2020 12:00'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '24 Nov 2020 11:59'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	18 Nov 2020 19:26:05
User entered 'Day 7'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49



US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:41:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:41:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '24 Nov 2020 12:00'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '25 Nov 2020 11:59'	System	18 Nov 2020 19:26:05



US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	18 Nov 2020 19:26:05
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-18T14:51:46', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '8a5db169-f33e-4296-a1ab-fb68ebc06745' User entered 'None (0)'	System	18 Nov 2020 19:52:00
	System	18 Nov 2020 19:52:00

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-18T14:51:48', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '8a5db169-f33e-4296-a1ab-fb68ebc06745' User entered 'None (0)'	System	18 Nov 2020 19:52:00
	System	18 Nov 2020 19:52:00

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-18T14:51:49', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '8a5db169-f33e-4296-a1ab-fb68ebc06745' User entered 'None (0)'	System	18 Nov 2020 19:52:00
	System	18 Nov 2020 19:52:00

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-18T14:51:50', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '8a5db169-f33e-4296-a1ab-fb68ebc06745' User entered 'None (0)'	System	18 Nov 2020 19:52:00
	System	18 Nov 2020 19:52:00

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-18T14:51:52', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '8a5db169-f33e-4296-a1ab-fb68ebc06745' User entered 'None (0)'	System	18 Nov 2020 19:52:00
	System	18 Nov 2020 19:52:00

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-18T14:51:53', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '8a5db169-f33e-4296-a1ab-fb68ebc06745' User entered 'None (0)'	System	18 Nov 2020 19:52:00
	System	18 Nov 2020 19:52:00

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-18T14:51:55', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '8a5db169-f33e-4296-a1ab-fb68ebc06745' User entered 'No (N)'	System	18 Nov 2020 19:52:00
	System	18 Nov 2020 19:52:00



US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-18T14:51:57', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '8a5db169-f33e-4296-a1ab-fb68ebc06745' User entered '18 Nov 2020 14:51'	System	18 Nov 2020 19:52:00
	System	18 Nov 2020 19:52:00

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '18 Nov 2020 14:37'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '18 Nov 2020 17:07'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	18 Nov 2020 19:26:05
User entered 'Day 1, after vaccination (at home)'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-18T19:01:31', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '31847f7e-c790-4c86-a295-77f7eee8dafb'	System	19 Nov 2020 00:01:50
User entered 'No interference with activity (1)'	System	19 Nov 2020 00:01:50

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-18T19:01:33', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '31847f7e-c790-4c86-a295-77f7eee8dafb' User entered 'None (0)'	System	19 Nov 2020 00:01:50
	System	19 Nov 2020 00:01:50

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-18T19:01:37', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '31847f7e-c790-4c86-a295-77f7eee8dafb' User entered 'None (0)'	System	19 Nov 2020 00:01:50
	System	19 Nov 2020 00:01:50

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-18T19:01:40', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '31847f7e-c790-4c86-a295-77f7eee8dafb' User entered 'None (0)'	System	19 Nov 2020 00:01:50
	System	19 Nov 2020 00:01:50



US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-18T19:01:41', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '31847f7e-c790-4c86-a295-77f7eee8dafb' User entered 'None (0)'	System	19 Nov 2020 00:01:50
	System	19 Nov 2020 00:01:50

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-18T19:01:43', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '31847f7e-c790-4c86-a295-77f7eee8dafb' User entered 'None (0)'	System	19 Nov 2020 00:01:50
	System	19 Nov 2020 00:01:50

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-18T19:01:45', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '31847f7e-c790-4c86-a295-77f7eee8dafb' User entered 'No (N)'	System	19 Nov 2020 00:01:50
	System	19 Nov 2020 00:01:50

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-18T19:01:47', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '31847f7e-c790-4c86-a295-77f7eee8dafb' User entered '18 Nov 2020 19:01'	System	19 Nov 2020 00:01:50
	System	19 Nov 2020 00:01:50

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '18 Nov 2020 18:02'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '19 Nov 2020 11:59'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	18 Nov 2020 19:26:05
User entered 'Day 2'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-19T14:29:03', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '8b0d2cc6-4377-4637-98a4-d089f56a0f00'	System	19 Nov 2020 19:29:31
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	19 Nov 2020 19:29:31



US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-19T14:29:08', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '8b0d2cc6-4377-4637-98a4-d089f56a0f00'	System	19 Nov 2020 19:29:31
User entered 'Some interference with activity (2)'	System	19 Nov 2020 19:29:31

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-19T14:29:13', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '8b0d2cc6-4377-4637-98a4-d089f56a0f00'	System	19 Nov 2020 19:29:31
User entered 'Some interference with activity (2)'	System	19 Nov 2020 19:29:31

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-19T14:29:17', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '8b0d2cc6-4377-4637-98a4-d089f56a0f00' User entered 'None (0)'	System	19 Nov 2020 19:29:31
	System	19 Nov 2020 19:29:31

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-19T14:29:19', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '8b0d2cc6-4377-4637-98a4-d089f56a0f00' User entered 'None (0)'	System	19 Nov 2020 19:29:31
	System	19 Nov 2020 19:29:31

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-19T14:29:21', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '8b0d2cc6-4377-4637-98a4-d089f56a0f00' User entered 'None (0)'	System	19 Nov 2020 19:29:31
	System	19 Nov 2020 19:29:31

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-19T14:29:24', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '8b0d2cc6-4377-4637-98a4-d089f56a0f00' User entered 'No (N)'	System	19 Nov 2020 19:29:31
	System	19 Nov 2020 19:29:31

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-11-19T14:29:28', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '8b0d2cc6-4377-4637-98a4-d089f56a0f00' User entered '19 Nov 2020 14:29'	System	19 Nov 2020 19:29:31
	System	19 Nov 2020 19:29:31

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '19 Nov 2020 12:00'	System	18 Nov 2020 19:26:05



US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '20 Nov 2020 11:59'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	18 Nov 2020 19:26:05
User entered 'Day 3'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49



US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '20 Nov 2020 12:00'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '21 Nov 2020 11:59'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	18 Nov 2020 19:26:05
User entered 'Day 4'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49



US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '21 Nov 2020 12:00'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '22 Nov 2020 11:59'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	18 Nov 2020 19:26:05
User entered 'Day 5'	System	18 Nov 2020 19:26:05



US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49



US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '22 Nov 2020 12:00'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '23 Nov 2020 11:59'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	18 Nov 2020 19:26:05
User entered 'Day 6'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49



US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '23 Nov 2020 12:00'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '24 Nov 2020 11:59'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:33

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
Data entry locked.	System	18 Nov 2020 19:26:05
User entered 'Day 7'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:33

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:33

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49



US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:33

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:33

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:33

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:33

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:33

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 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '24 Nov 2020 12:00'	System	18 Nov 2020 19:26:05

US3432627

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:41:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:35:49
User entered '25 Nov 2020 11:59'	System	18 Nov 2020 19:26:05



US3432627

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	30 Nov 2020 15:08:11

US3432627

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '25 Nov 2020'	Phoebe Cunningham (b) (4)	30 Nov 2020 15:08:11

US3432627

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Contact Not Made (CONTACT NOT MADE)'	Phoebe Cunningham (b) (4)	30 Nov 2020 15:08:11

US3432627

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Pt called at 8:40 and 12:11 on 25NOV2020 and 9:49 and 1:53 on 27NOV2020.'	Phoebe Cunningham (b) (4)	30 Nov 2020 15:08:11

US3432627

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	30 Nov 2020 15:08:17

US3432627

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'I'	System	30 Nov 2020 15:08:17

US3432627

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	02 Dec 2020 15:42:22

US3432627

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '2 Dec 2020'	Kathleen Garvey (b) (4)	02 Dec 2020 15:42:22



US3432627

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Contact Made (CONTACT MADE)'	Kathleen Garvey (b) (4)	02 Dec 2020 15:42:22

US3432627

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered empty.	Kathleen Garvey (b) (4)	02 Dec 2020 15:42:22

US3432627

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	02 Dec 2020 15:42:28

US3432627

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'I'	System	02 Dec 2020 15:42:28

US3432627

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	09 Dec 2020 19:07:45

US3432627

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '9 Dec 2020'	Kathleen Garvey (b) (4)	09 Dec 2020 19:07:45

US3432627

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Contact Made (CONTACT MADE)'	Kathleen Garvey (b) (4)	09 Dec 2020 19:07:45

US3432627

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered empty.	Kathleen Garvey (b) (4)	09 Dec 2020 19:07:45



US3432627

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	09 Dec 2020 19:07:50

US3432627

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'I'	System	09 Dec 2020 19:07:50

US3432627

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Dec 2020 20:26:43

US3432627

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:33

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '17 Dec 2020'	(b) (4), (b) (6)	17 Dec 2020 20:26:43

US3432627

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:33

[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 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	17 Dec 2020 20:26:43

US3432627

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'VISIT3'	System	17 Dec 2020 20:26:43

US3432627

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Dec 2020 20:53:55

US3432627

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '17 Dec 2020'	(b) (4), (b) (6)	17 Dec 2020 20:53:55



US3432627

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:33

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '15:04'	(b) (4), (b) (6)	17 Dec 2020 20:53:55

US3432627

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered '17 Dec 2020 15:04'	System	17 Dec 2020 20:53:55

US3432627

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '98.4' F	(b) (4), (b) (6)	17 Dec 2020 20:53:55

US3432627

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Oral (Oral)'	(b) (4), (b) (6)	17 Dec 2020 20:53:55

US3432627

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered empty.	(b) (4), (b) (6)	17 Dec 2020 20:53:55

US3432627

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '84'	(b) (4), (b) (6)	17 Dec 2020 20:53:55

US3432627

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'bpm'	System	17 Dec 2020 20:53:55

US3432627

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '14'	(b) (4), (b) (6)	17 Dec 2020 20:53:55



US3432627

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'breaths/min'	System	17 Dec 2020 20:53:55

US3432627

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '121'	(b) (4), (b) (6)	17 Dec 2020 20:53:55

US3432627

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'mmHg'	System	17 Dec 2020 20:53:55

US3432627

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:33

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '073'	(b) (4), (b) (6)	17 Dec 2020 20:53:55

US3432627

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:33

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'mmHg'	System	17 Dec 2020 20:53:55

US3432627

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:33

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52

US3432627

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:41:33

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52

US3432627

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'No (N)'	(b) (4), (b) (6)	17 Dec 2020 20:54:19



US3432627

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:41:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered empty.	(b) (4), (b) (6)	17 Dec 2020 20:54:19

US3432627

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Dec 2020 20:54:47

US3432627

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '17 Dec 2020'	(b) (4), (b) (6)	17 Dec 2020 20:54:47

US3432627

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '15:25'	(b) (4), (b) (6)	17 Dec 2020 20:54:47

US3432627

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered '17 Dec 2020 15:25'	System	17 Dec 2020 20:54:47

US3432627

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Dec 2020 20:54:56

US3432627

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'I'	System	17 Dec 2020 20:54:56

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 13:20:24



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-12-21T14:36:40', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '2e5c5b9d-ac39-44c9-803b-75d2cdeb9744' User entered 'No (N)'	System	21 Dec 2020 19:36:48
	System	21 Dec 2020 19:36:48

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

Have you been exposed to someone with 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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-12-21T14:36:37', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '2e5c5b9d-ac39-44c9-803b-75d2cdeb9744' User entered 'No (N)'	System	21 Dec 2020 19:36:48
	System	21 Dec 2020 19:36:48

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-12-21T14:36:44', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '2e5c5b9d-ac39-44c9-803b-75d2cdeb9744' User entered '21 Dec 2020 14:36:44'	System	21 Dec 2020 19:36:48
	System	21 Dec 2020 19:36:48

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-12-27T21:30:13', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '972c2148-9d66-4e79-9a40-f9b8f33adbe2' User entered 'No (N)'	System	28 Dec 2020 02:30:22
	System	28 Dec 2020 02:30:22

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

Have you been exposed to someone with 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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-12-27T21:30:16', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '972c2148-9d66-4e79-9a40-f9b8f33adbe2' User entered 'No (N)'	System	28 Dec 2020 02:30:22
	System	28 Dec 2020 02:30:22



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2020-12-27T21:30:18', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '972c2148-9d66-4e79-9a40-f9b8f33adbe2' User entered '27 Dec 2020 21:30:18'	System	28 Dec 2020 02:30:22
	System	28 Dec 2020 02:30:22

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-01-05T11:59:21', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'e442f4ed-ad59-4cdd-b317-8e55f2e5a09c'	System	05 Jan 2021 16:59:35
User entered 'No (N)'	System	05 Jan 2021 16:59:35

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

Have you been exposed to someone with 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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-01-05T11:59:27', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'e442f4ed-ad59-4cdd-b317-8e55f2e5a09c'	System	05 Jan 2021 16:59:35
User entered 'No (N)'	System	05 Jan 2021 16:59:35

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-01-05T11:59:29', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'e442f4ed-ad59-4cdd-b317-8e55f2e5a09c' User entered '05 Jan 2021 11:59:29'	System	05 Jan 2021 16:59:35
	System	05 Jan 2021 16:59:35

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 13:20:24



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 13:20:24

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

[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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-01-11T14:21:36', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'ee9be628-f0d3-4526-925d-1997edefb565'	System	11 Jan 2021 19:21:43
User entered 'No (N)'	System	11 Jan 2021 19:21:43

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

Have you been exposed to someone with 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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-01-11T14:21:38', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'ee9be628-f0d3-4526-925d-1997edefb565'	System	11 Jan 2021 19:21:43
User entered 'No (N)'	System	11 Jan 2021 19:21:43

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-01-11T14:21:40', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'ee9be628-f0d3-4526-925d-1997edefb565' User entered '11 Jan 2021 14:21:40'	System	11 Jan 2021 19:21:43
	System	11 Jan 2021 19:21:43

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 13:20:24



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-01-18T10:32:37', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '3a299e63-3110-4bad-85c2-d5585882c385' User entered 'No (N)'	System	18 Jan 2021 15:32:43

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

Have you been exposed to someone with 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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-01-18T10:32:39', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '3a299e63-3110-4bad-85c2-d5585882c385' User entered 'No (N)'	System	18 Jan 2021 15:32:43

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-01-18T10:32:41', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '3a299e63-3110-4bad-85c2-d5585882c385' User entered '18 Jan 2021 10:32:41'	System	18 Jan 2021 15:32:43
	System	18 Jan 2021 15:32:43

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-01-24T17:58:05', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '2f44409f-dba7-432a-b009-a5b0eed778e9' User entered 'No (N)'	System	25 Jan 2021 22:09:13
	System	25 Jan 2021 22:09:13

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

Have you been exposed to someone with 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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-01-24T17:58:07', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '2f44409f-dba7-432a-b009-a5b0eed778e9' User entered 'No (N)'	System	25 Jan 2021 22:09:13



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-01-24T17:58:09', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '2f44409f-dba7-432a-b009-a5b0eed778e9' User entered '24 Jan 2021 17:58:09'	System	25 Jan 2021 22:09:13
	System	25 Jan 2021 22:09:13

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-02-01T16:03:10', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '78942c93-c0f9-4d62-ae1d-d1383dea1a2b' User entered 'No (N)'	System	01 Feb 2021 21:05:30
	System	01 Feb 2021 21:05:30

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Have you been exposed to someone with 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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-02-01T16:03:11', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '78942c93-c0f9-4d62-ae1d-d1383dea1a2b' User entered 'No (N)'	System	01 Feb 2021 21:05:30
	System	01 Feb 2021 21:05:30

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-02-01T16:03:13', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '78942c93-c0f9-4d62-ae1d-d1383dea1a2b' User entered '01 Feb 2021 16:03:13'	System	01 Feb 2021 21:05:30
	System	01 Feb 2021 21:05:30

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 13:20:24



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-02-06T20:14:31', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'bda373a3-5bd4-4e3a-8892-722b962b866f' User entered 'No (N)'	System	07 Feb 2021 01:14:38
	System	07 Feb 2021 01:14:38

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

Have you been exposed to someone with 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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-02-06T20:14:32', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'bda373a3-5bd4-4e3a-8892-722b962b866f' User entered 'No (N)'	System	07 Feb 2021 01:14:38
	System	07 Feb 2021 01:14:38

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-02-06T20:14:35', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'bda373a3-5bd4-4e3a-8892-722b962b866f' User entered '06 Feb 2021 20:14:35'	System	07 Feb 2021 01:14:38
	System	07 Feb 2021 01:14:38

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 13:20:24



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-02-13T20:56:23', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '53c1cd20-c197-4908-956b-7417cc4ad128'	System	14 Feb 2021 01:56:39
User entered 'Yes (Y)'	System	14 Feb 2021 01:56:39

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

Have you been exposed to someone with 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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-02-13T20:56:25', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '53c1cd20-c197-4908-956b-7417cc4ad128' User entered 'No (N)'	System	14 Feb 2021 01:56:39

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-02-13T20:56:27', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '53c1cd20-c197-4908-956b-7417cc4ad128'	System	14 Feb 2021 01:56:39
User entered 'No (N)'	System	14 Feb 2021 01:56:39

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-02-13T20:56:31', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '53c1cd20-c197-4908-956b-7417cc4ad128' User entered 'No (N)'	System	14 Feb 2021 01:56:39

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-02-13T20:56:37', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '53c1cd20-c197-4908-956b-7417cc4ad128'	System	14 Feb 2021 01:56:39
User entered '13 Feb 2021 20:56:37'	System	14 Feb 2021 01:56:39

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 13:20:24



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-02-22T18:04:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'f90b8649-506d-453d-8073-38c008ead83b' User entered 'No (N)'	System	22 Feb 2021 23:09:01
	System	22 Feb 2021 23:09:01

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

Have you been exposed to someone with 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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-02-22T18:04:01', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'f90b8649-506d-453d-8073-38c008ead83b' User entered 'No (N)'	System	22 Feb 2021 23:09:01
	System	22 Feb 2021 23:09:01

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-02-22T18:04:03', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'f90b8649-506d-453d-8073-38c008ead83b' User entered '22 Feb 2021 18:04:03'	System	22 Feb 2021 23:09:01
	System	22 Feb 2021 23:09:01

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-03-02T12:13:17-05:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '3617ae7c-6401-48b4-a34e-5c75afa8739b'	System	02 Mar 2021 17:18:05
User entered 'No (N)'	System	02 Mar 2021 17:18:05

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

Have you been exposed to someone with 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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-03-02T12:13:19-05:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '3617ae7c-6401-48b4-a34e-5c75afa8739b'	System	02 Mar 2021 17:18:05
User entered 'No (N)'	System	02 Mar 2021 17:18:05



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-03-02T12:13:23-05:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '3617ae7c-6401-48b4-a34e-5c75afa8739b' User entered '02 Mar 2021 12:13:23'	System	02 Mar 2021 17:18:05
	System	02 Mar 2021 17:18:05

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-03-07T13:28:14-05:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'b717ebe2-b298-499f-98fd-702d4a52eb04'	System	07 Mar 2021 18:28:22
User entered 'No (N)'	System	07 Mar 2021 18:28:22

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

Have you been exposed to someone with 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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-03-07T13:28:16-05:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'b717ebe2-b298-499f-98fd-702d4a52eb04'	System	07 Mar 2021 18:28:22
User entered 'No (N)'	System	07 Mar 2021 18:28:22

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-03-07T13:28:18-05:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'b717ebe2-b298-499f-98fd-702d4a52eb04'	System	07 Mar 2021 18:28:22
User entered '07 Mar 2021 13:28:18'	System	07 Mar 2021 18:28:22

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 13:20:24



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-03-12T12:24:27-05:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'b184b991-039e-445d-a912-efd54bc3ad8f'	System	12 Mar 2021 17:24:38
User entered 'No (N)'	System	12 Mar 2021 17:24:38

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

Have you been exposed to someone with 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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-03-12T12:24:28-05:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'b184b991-039e-445d-a912-efd54bc3ad8f'	System	12 Mar 2021 17:24:38
User entered 'No (N)'	System	12 Mar 2021 17:24:38

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-03-12T12:24:33-05:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'b184b991-039e-445d-a912-efd54bc3ad8f'	System	12 Mar 2021 17:24:38
User entered '12 Mar 2021 12:24:33'	System	12 Mar 2021 17:24:38

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 13:20:24



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-03-19T18:40:18-04:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'f79a9705-21bb-450f-8d67-feaeb21075ac'	System	19 Mar 2021 22:40:40
User entered 'No (N)'	System	19 Mar 2021 22:40:40

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

Have you been exposed to someone with 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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-03-19T18:40:34-04:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'f79a9705-21bb-450f-8d67-feaeb21075ac'	System	19 Mar 2021 22:40:40
User entered 'No (N)'	System	19 Mar 2021 22:40:40

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-03-19T18:40:36-04:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'f79a9705-21bb-450f-8d67-feaeb21075ac' User entered '19 Mar 2021 18:40:36'	System	19 Mar 2021 22:40:40
	System	19 Mar 2021 22:40:40

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-03-29T17:05:34-04:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'ed1b7d07-d52e-41b1-8069-d0f803fc0a53'	System	29 Mar 2021 21:06:33
User entered 'Yes (Y)'	System	29 Mar 2021 21:06:33

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

Have you been exposed to someone with 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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-03-29T17:05:44-04:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'ed1b7d07-d52e-41b1-8069-d0f803fc0a53'	System	29 Mar 2021 21:06:33
User entered 'No (N)'	System	29 Mar 2021 21:06:33



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-03-29T17:05:50-04:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'ed1b7d07-d52e-41b1-8069-d0f803fc0a53'	System	29 Mar 2021 21:06:33
User entered 'No (N)'	System	29 Mar 2021 21:06:33

US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-03-29T17:05:59-04:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'ed1b7d07-d52e-41b1-8069-d0f803fc0a53'	System	29 Mar 2021 21:06:33
User entered 'Yes (Y)'	System	29 Mar 2021 21:06:33

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-03-29T17:06:10-04:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'ed1b7d07-d52e-41b1-8069-d0f803fc0a53'	System	29 Mar 2021 21:06:33
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Mar 2021 21:06:33

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-03-29T17:06:19-04:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'ed1b7d07-d52e-41b1-8069-d0f803fc0a53'	System	29 Mar 2021 21:06:33
User entered '29 Mar 2021 17:06:19'	System	29 Mar 2021 21:06:33

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-04-05T17:41:06-04:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '4588a53e-ced2-47e4-8df6-b9a539e94d7e' User entered 'Yes (Y)'	System	05 Apr 2021 21:41:25
	System	05 Apr 2021 21:41:25



US3432627

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:41:33

Have you been exposed to someone with 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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-04-05T17:41:09-04:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '4588a53e-ced2-47e4-8df6-b9a539e94d7e' User entered 'No (N)'	System	05 Apr 2021 21:41:25
	System	05 Apr 2021 21:41:25

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-04-05T17:41:14-04:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '4588a53e-ced2-47e4-8df6-b9a539e94d7e' User entered 'No (N)'	System	05 Apr 2021 21:41:25
	System	05 Apr 2021 21:41:25

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-04-05T17:41:18-04:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '4588a53e-ced2-47e4-8df6-b9a539e94d7e' User entered 'No (N)'	System	05 Apr 2021 21:41:25
	System	05 Apr 2021 21:41:25

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-04-05T17:41:21-04:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '4588a53e-ced2-47e4-8df6-b9a539e94d7e' User entered '05 Apr 2021 17:41:21'	System	05 Apr 2021 21:41:25
	System	05 Apr 2021 21:41:25

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-04-09T15:54:50-04:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '9a9ae947-40ef-4437-b5a2-6c5d276fe769' User entered 'No (N)'	System	09 Apr 2021 19:55:04



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

Have you been exposed to someone with 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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-04-09T15:54:52-04:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '9a9ae947-40ef-4437-b5a2-6c5d276fe769'	System	09 Apr 2021 19:55:04
User entered 'No (N)'	System	09 Apr 2021 19:55:04

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-04-09T15:54:59-04:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '9a9ae947-40ef-4437-b5a2-6c5d276fe769'	System	09 Apr 2021 19:55:04
User entered '09 Apr 2021 15:54:59'	System	09 Apr 2021 19:55:04

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-04-17T11:09:24-04:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'e617a02e-e48c-4e61-b1be-07e4e49f967b' User entered 'No (N)'	System	17 Apr 2021 15:09:32
	System	17 Apr 2021 15:09:32

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Have you been exposed to someone with 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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-04-17T11:09:26-04:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'e617a02e-e48c-4e61-b1be-07e4e49f967b' User entered 'No (N)'	System	17 Apr 2021 15:09:32

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-04-17T11:09:28-04:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'e617a02e-e48c-4e61-b1be-07e4e49f967b' User entered '17 Apr 2021 11:09:28'	System	17 Apr 2021 15:09:32
	System	17 Apr 2021 15:09:32



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-04-25T12:03:27-04:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'b96f23ea-ad25-467e-967c-aeb60e8b3326'	System	25 Apr 2021 16:07:54
User entered 'No (N)'	System	25 Apr 2021 16:07:54

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

Have you been exposed to someone with 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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-04-25T12:03:29-04:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'b96f23ea-ad25-467e-967c-aeb60e8b3326'	System	25 Apr 2021 16:07:54
User entered 'No (N)'	System	25 Apr 2021 16:07:54

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-04-25T12:03:32-04:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'b96f23ea-ad25-467e-967c-aeb60e8b3326' User entered '25 Apr 2021 12:03:32'	System	25 Apr 2021 16:07:54
	System	25 Apr 2021 16:07:54

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 13:20:24



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-04-30T13:00:05-04:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'e13a9136-2660-497f-885b-e0c90daf4584'	System	30 Apr 2021 17:00:41
User entered 'Yes (Y)'	System	30 Apr 2021 17:00:41

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

Have you been exposed to someone with 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 (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-04-30T13:00:08-04:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'e13a9136-2660-497f-885b-e0c90daf4584' User entered 'No (N)'	System	30 Apr 2021 17:00:41

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-04-30T13:00:13-04:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'e13a9136-2660-497f-885b-e0c90daf4584' User entered 'No (N)'	System	30 Apr 2021 17:00:41
	System	30 Apr 2021 17:00:41

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-04-30T13:00:18-04:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'e13a9136-2660-497f-885b-e0c90daf4584' User entered 'No (N)'	System	30 Apr 2021 17:00:41

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-04-30T13:00:21-04:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: 'e13a9136-2660-497f-885b-e0c90daf4584' User entered '30 Apr 2021 13:00:21'	System	30 Apr 2021 17:00:41
	System	30 Apr 2021 17:00:41

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 13:20:24



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 13:20:24



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 13:20:24



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 13:20:24



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 13:20:24



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 13:20:24



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 13:20:24



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 13:20:24



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 13:20:24



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 13:20:24



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 13:20:24



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 13:20:24



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 13:20:24



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 13:20:24



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 13:20:24



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 13:20:24



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 13:20:24



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 13:20:24



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 13:20:24



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 13:20:24



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 13:20:24



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 13:20:24



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 13:20:24



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 13:20:24



**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 13:20:24



**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 13:20:24



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 13:20:24



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 13:20:24



**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 13:20:24



**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 13:20:24



**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 13:20:24



**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '18 Nov 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '22 Nov 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '25 Nov 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '29 Nov 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '02 Dec 2022 00:01'	System	20 Nov 2020 13:20:24



**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '06 Dec 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '09 Dec 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '13 Dec 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '16 Dec 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '20 Dec 2022 23:59'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 13:20:24



**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '23 Dec 2022 00:01'	System	20 Nov 2020 13:20:24

**US3432627**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:41:33**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:20:24
Amendment Manager: User entered '27 Dec 2022 23:59'	System	20 Nov 2020 13:20:24

US3432627

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:41:33**

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 06:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-03-02T12:13:30-05:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '7b80a747-d8c1-4967-8bc2-8493fb12faac'	System	02 Mar 2021 17:18:14
User entered 'No (N)'	System	02 Mar 2021 17:18:14

US3432627

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:41:33

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:24:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (3668478F-97F8-4E15-98AB-444DE218FA8D)', Time: '2021-03-02T12:13:32-05:00', User OID: 'PatientReportedOutcome (US3432627)', ODM File OID: '7b80a747-d8c1-4967-8bc2-8493fb12faac' User entered '02 Mar 2021 12:13:32'	System	02 Mar 2021 17:18:14
	System	02 Mar 2021 17:18:14

US3432627

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Jan 2021 20:03:03

US3432627

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered '13 Jan 2021'	(b) (4), (b) (6)	13 Jan 2021 20:03:03

US3432627

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	13 Jan 2021 20:03:03

US3432627

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 20:03:03



US3432627

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Jan 2021 20:03:08

US3432627

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 04:02:52
User entered 'I'	System	13 Jan 2021 20:03:08

US3432627

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:46:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Feb 2021 18:27:48

US3432627

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:46:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered '16 Feb 2021'	(b) (4), (b) (6)	16 Feb 2021 18:27:48

US3432627

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:46:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	16 Feb 2021 18:27:48

US3432627

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:46:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 18:27:48

US3432627

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:46:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Feb 2021 18:27:53

US3432627

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:46:37
User entered 'I'	System	16 Feb 2021 18:27:53



US3432627

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:46:37
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
User entered 'Yes (Y)'	Tenaizus Woods (b) (4)	19 Mar 2021 18:26:39

US3432627

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:46:37
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
User entered '19 Mar 2021'	Tenaizus Woods (b) (4)	19 Mar 2021 18:26:39

US3432627

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:46:37
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
User entered 'Contact Made (CONTACT MADE)'	Tenaizus Woods (b) (4)	19 Mar 2021 18:26:39

US3432627

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:46:37
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
User entered empty.	Tenaizus Woods (b) (4)	19 Mar 2021 18:26:39

US3432627

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:46:37
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
User entered 'Yes (Y)'	Tenaizus Woods (b) (4)	19 Mar 2021 18:26:47

US3432627

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:46:37
User entered 'I'	System	19 Mar 2021 18:26:47

US3432627

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:30:22
User entered 'Yes (Y)'	Bethany Evans (b) (4) (b) (4)	21 Apr 2021 15:37:39

US3432627

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:30:22
User entered '19 Apr 2021'	Bethany Evans (b) (4) (b) (4)	21 Apr 2021 15:37:39



US3432627

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:30:22
User entered 'Contact Not Made (CONTACT NOT MADE)'	Bethany Evans (b) (4) (b) (4)	21 Apr 2021 15:37:39

US3432627

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:41:33

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:30:22
User entered 'attempted to contact pt for safety call - contact was not made. pt was called 14APR21 @14:17, 16APR21 @10:38 and 19APR21 @11:58'	Bethany Evans (b) (4)	21 Apr 2021 15:37:39
	(b) (4)	

US3432627

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:41:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:30:22
User entered 'Yes (Y)'	Bethany Evans (b) (4) (b) (4)	21 Apr 2021 15:37:46

**US3432627**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:41:33**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Apr 2021 15:37:46

US3432627

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	23 Jan 2021 18:04:49

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered '23 Jan 2021'	Bruce Bausk (b) (4)	23 Jan 2021 18:04:49

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:41:33

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered 'Clinic (Clinic)'	Bruce Bausk (b) (4)	23 Jan 2021 18:04:49

**US3432627**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:41:33**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User entered 'UNBLND_DECIDE'	System	23 Jan 2021 18:04:49



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:41:33

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered '23 Jan 2021'	Bruce Bausk (b) (4)	23 Jan 2021 18:05:01

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:41:33

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:30:22
User entered '0'	Monica Feeley (b) (4)	05 Apr 2021 21:00:35
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 09:56:40

US3432627

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:41:33

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	23 Jan 2021 18:05:01

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:41:33

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:30:22
User entered 'Amendment 6 or later (Amendment 6 or later)'	Monica Feeley (b) (4)	05 Apr 2021 21:00:35
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:56:40

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:41:33

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered '23 Jan 2021'	Bruce Bausk (b) (4)	23 Jan 2021 18:05:01

US3432627

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:41:33

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered 'mRNA-1273 (mRNA-1273)'	Bruce Bausk (b) (4)	23 Jan 2021 18:05:01

US3432627

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:41:33

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered 'mRNA-1273 (mRNA-1273)'	Bruce Bausk (b) (4)	23 Jan 2021 18:05:01

US3432627

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:41:33

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered 'mRNA-1273 (mRNA-1273)'	Bruce Bausk (b) (4)	23 Jan 2021 18:05:01



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:41:33

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered 'No (N)'	Bruce Bausk (b) (4)	23 Jan 2021 18:05:01

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:41:33

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User entered empty.	System	23 Jan 2021 18:05:01

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:41:33

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User entered empty.	System	23 Jan 2021 18:05:01

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	23 Jan 2021 18:05:53

US3432627

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered '23 Jan 2021'	Bruce Bausk (b) (4)	23 Jan 2021 18:05:53

US3432627

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:33

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered '11:30'	Bruce Bausk (b) (4)	23 Jan 2021 18:05:53

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:41:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User entered '23 Jan 2021 11:30'	System	23 Jan 2021 18:05:53

US3432627

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:41:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	23 Jan 2021 18:06:00



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:41:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered '23 Jan 2021'	Bruce Bausk (b) (4)	23 Jan 2021 18:06:00

US3432627

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:41:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered '11:46'	Bruce Bausk (b) (4)	23 Jan 2021 18:06:00

**US3432627**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:41:33**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:08
User entered '23 Jan 2021 11:46'	System	23 Jan 2021 18:06:00

US3432627

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:41:33

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:58:26
User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 159 (29MAR2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 13:37:30
Query 'Per DM CLR: Per Safety Follow Up Diary Day 159 (29MAR2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'Updated. UTI AE is already recorded and captured on EDC and source documentation.' (Site from DM).	Tenaizus Woods (b) (4) (b) (4)	07 Apr 2021 12:54:23
User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 159 (29MAR2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 13:49:32
User signature succeeded.	Lindsey Baden (b) (4) (b) (4)	19 Feb 2021 03:35:08
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	21 Oct 2020 19:34:37

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:33

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:16

US3432627

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:33

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Pruritus NEC, PT: Pruritus, LLT: Pruritus - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 19:38:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 19:38:39
Data point term sent to Coder	System	21 Oct 2020 19:37:30
User entered 'left arm pruritus'	Julia Klopfer (b) (4)	21 Oct 2020 19:37:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	21 Oct 2020 19:37:20

US3432627

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered 'No (N)'	Julia Klopfer (b) (4)	21 Oct 2020 19:37:20



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered 'No (N)'	Julia Klopfer (b) (4)	21 Oct 2020 19:37:20

US3432627

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered '21 Oct 2020'	Julia Klopfer (b) (4)	21 Oct 2020 19:37:20

US3432627

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:33

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered '12:20'	Julia Klopfer (b) (4)	21 Oct 2020 19:37:20

US3432627

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:33

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:16
User entered '21 Oct 2020 12:20'	System	21 Oct 2020 19:37:20

US3432627

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered 'No (N)' reason for change: Data Entry Error	Julia Klopfer (b) (4)	22 Oct 2020 15:48:11
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	21 Oct 2020 19:37:20

US3432627

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	22 Oct 2020 15:48:25
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	22 Oct 2020 15:48:25
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	22 Oct 2020 15:48:11
User entered '21 Oct 2020' reason for change: Data Entry Error	Julia Klopfer (b) (4)	22 Oct 2020 15:48:11
User entered empty.	Julia Klopfer (b) (4)	21 Oct 2020 19:37:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:33

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered '17:45' reason for change: Data Entry Error	Julia Klopfer (b) (4)	22 Oct 2020 15:48:11
User entered empty.	Julia Klopfer (b) (4)	21 Oct 2020 19:37:20

US3432627

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:33

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:16
User entered '21 Oct 2020 17:45'	System	22 Oct 2020 15:48:11
User entered empty.	System	21 Oct 2020 19:37:20



US3432627

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:33

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered 'Grade 1/Mild (Grade 1/Mild)'	Julia Klopfer (b) (4)	21 Oct 2020 19:37:20

US3432627

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered 'No (N)'	Julia Klopfer (b) (4)	21 Oct 2020 19:37:20

US3432627

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:33

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered '0'	Julia Klopfer (b) (4)	21 Oct 2020 19:37:20

US3432627

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:33

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered '0'	Julia Klopfer (b) (4)	21 Oct 2020 19:37:20

US3432627

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered '0'	Julia Klopfer (b) (4)	21 Oct 2020 19:37:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered empty.	Julia Klopfer (b) (4)	21 Oct 2020 19:37:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:33

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered empty.	Julia Klopfer (b) (4)	21 Oct 2020 19:37:20

**US3432627**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:41:33**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered empty.	Julia Klopfer (b) (4)	21 Oct 2020 19:37:20



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered empty.	Julia Klopfer (b) (4)	21 Oct 2020 19:37:20

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered '0'	Julia Klopfer (b) (4)	21 Oct 2020 19:37:20

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered '0'	Julia Klopfer (b) (4)	21 Oct 2020 19:37:20

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered '0'	Julia Klopfer (b) (4)	21 Oct 2020 19:37:20

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered 'Not Related (NOT RELATED)'	Julia Klopfer (b) (4)	21 Oct 2020 19:37:20

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered 'Related (RELATED)'	Julia Klopfer (b) (4)	21 Oct 2020 19:37:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:33

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered 'None (NONE)'	Julia Klopfer (b) (4)	21 Oct 2020 19:37:20

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Folder: Adverse Events

Form: Adverse Events (1)

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered 'l'	Julia Klopfer (b) (4)	21 Oct 2020 19:37:20



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered '0'	Julia Klopfer (b) (4)	21 Oct 2020 19:37:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered '0'	Julia Klopfer (b) (4)	21 Oct 2020 19:37:20

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Julia Klopfer (b) (4)	22 Oct 2020 15:48:25
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Julia Klopfer (b) (4)	21 Oct 2020 19:37:20

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Folder: Adverse Events

Form: Adverse Events (1)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered empty.	Julia Klopfer (b) (4)	21 Oct 2020 19:37:20

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:16
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered empty.	Julia Klopfer (b) (4)	21 Oct 2020 19:37:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:33

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:16
User entered '0'	System	21 Oct 2020 19:37:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:33

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:16
User entered '1'	System	21 Oct 2020 19:37:20

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:41:33

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:36:16



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:33

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 13:03:42
User entered	System	25 Nov 2020 13:03:38
'USA-US078-2020-mRNA-1273-P301000014'		
User entered 'New'	(b) (4), (b) (6)	25 Nov 2020 13:03:38

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Inguinal hernias, PT: Inguinal hernia, LLT: Left inguinal hernia - version MedDRA\\23.0.	Coder Import (b) (4)	12 Mar 2021 14:30:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. DataPoint Verified.	Coder Import (b) (4)	12 Mar 2021 14:30:45
	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Hernias NEC, PT: Hernia, LLT: Hernia - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 21:07:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 21:07:11
Data point term sent to Coder	System	24 Nov 2020 20:23:40
User entered 'hernia s/p left inguinal hernia repair'	(b) (4), (b) (6)	24 Nov 2020 20:23:32

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Nov 2020 20:23:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered 'No (N)'	(b) (4), (b) (6)	24 Nov 2020 20:23:32

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered 'No (N)'	(b) (4), (b) (6)	24 Nov 2020 20:23:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered '23 Nov 2020'	(b) (4), (b) (6)	24 Nov 2020 20:23:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:33

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 20:23:32

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 20:23:32



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	24 Nov 2020 20:24:57
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 20:24:57
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	24 Nov 2020 20:23:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Nov 2020 20:23:32

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Form: Adverse Events (2)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
	(b) (4), (b) (6)	
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	24 Nov 2020 20:23:54
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	24 Nov 2020 20:23:54
User entered '24 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 20:23:54
	(b) (4), (b) (6)	
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	24 Nov 2020 20:23:32
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 20:23:32
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 20:23:32

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:41:33**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 20:23:32

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Folder: Adverse Events

Form: Adverse Events (2)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	24 Nov 2020 20:23:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	24 Nov 2020 20:23:54
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	24 Nov 2020 20:23:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Nov 2020 20:23:32

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Folder: Adverse Events

Form: Adverse Events (2)

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 20:23:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 20:23:32



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		24 Nov 2020 20:23:54
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		24 Nov 2020 20:23:54
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 20:23:54
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	24 Nov 2020 20:23:32
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 20:23:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered '23 Nov 2020'	(b) (4), (b) (6)	24 Nov 2020 20:23:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:33

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered '24 Nov 2020'	(b) (4), (b) (6)	24 Nov 2020 20:23:32

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered 'No (N)'	(b) (4), (b) (6)	24 Nov 2020 20:23:32

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 20:23:32

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Folder: Adverse Events

Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 20:23:32

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 20:23:32

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 20:23:32



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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	24 Nov 2020 20:23:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	24 Nov 2020 20:23:32

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Folder: Adverse Events

Form: Adverse Events (2)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	24 Nov 2020 20:23:32

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Folder: Adverse Events

Form: Adverse Events (2)

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered '0'	(b) (4), (b) (6)	24 Nov 2020 20:23:32

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. Note that medications recorded in Con Med eCRF are for Post Op Pain and not for this AE.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 05:37:48
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. Note that medications recorded in Con Med eCRF are for Post Op Pain and not for this AE.' answered with 'please see con meds' (Site from DM).	Monica Feeley (b) (4)	04 Mar 2021 16:32:30
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. Note that medications recorded in Con Med eCRF are for Post Op Pain and not for this AE.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 11:30:58
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 04:55:57
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'added' (Site from DM).	Monica Feeley (b) (4)	22 Jan 2021 18:29:20

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Folder: Adverse Events

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 11:11:07
	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered 'I'	(b) (4), (b) (6)	24 Nov 2020 20:23:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered 'I'	(b) (4), (b) (6)	24 Nov 2020 20:23:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:33

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	24 Nov 2020 20:23:32



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:33

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 20:23:32

US3432627

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:33

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
User closed query 'Per DM CLR: SAE Narrative = HERNIA REPAIR. However, these information were not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 04:56:13
Query 'Per DM CLR: SAE Narrative = HERNIA REPAIR. However, these information were not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' answered with 'added' (Site from DM).	Monica Feeley (b) (4) (b) (4)	22 Jan 2021 18:29:27
User opened query 'Per DM CLR: SAE Narrative = HERNIA REPAIR. However, these information were not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 11:09:56
User closed query 'PV Query: Please confirm if the subject had a medical history of left inguinal hernia (prior to start of study) or if the subject had a new onset of left inguinal hernia. If considered MH, please add to MH eCRF.' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 21:41:13
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)	07 Jan 2021 21:41:11
Query 'PV Query: Please confirm if the subject had a medical history of left inguinal hernia (prior to start of study) or if the subject had a new onset of left inguinal hernia. If considered MH, please add to MH eCRF.' answered with 'no past medical history ' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	07 Jan 2021 15:42:06
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'No relevant laboratory results' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	07 Jan 2021 15:33:52
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:37:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:33

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please confirm if the subject had a medical history of left inguinal hernia (prior to start of study) or if the subject had a new onset of left inguinal hernia. If considered MH, please add to MH eCRF.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 20:32:14
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)	04 Dec 2020 20:31:23
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	24 Nov 2020 20:24:43
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	24 Nov 2020 20:24:43
User entered 'Participant seen and admitted for hernia repair. Participant discharged on 24NOV2020. reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 20:24:43
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	24 Nov 2020 20:23:32
User entered empty.	(b) (4), (b) (6)	24 Nov 2020 20:23:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:41:33

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	24 Nov 2020 20:23:32

**US3432627**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:41:33**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Nov 2020 20:23:32

**US3432627**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:41:33**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Nov 2020 20:23:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:33

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Urinary tract infections, PT: Urinary tract infection, LLT: UTI - version MedDRA\\23.0.	Coder Import (b) (4)	01 Apr 2021 22:07:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Apr 2021 22:07:10
Data point term sent to Coder	System	01 Apr 2021 22:06:12
User entered 'UTI'	Austin Kim (b) (4)	01 Apr 2021 22:05:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered 'Yes (Y)'	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:05:59



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered 'No (N)'	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:05:59

US3432627

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
User entered 'No (N)'	Austin Kim (b) (4)	01 Apr 2021 22:05:59
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered '30 Mar 2021'	Austin Kim (b) (4) [REDACTED]	01 Apr 2021 22:05:59

US3432627

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:33

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered empty.	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:05:59

**US3432627**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:41:33**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 22:05:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered 'Yes (Y)'	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:05:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:33

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered empty.	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:05:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:33

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered empty.	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:05:59



**US3432627**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:41:33**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 22:05:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:33

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:05:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered 'No (N)'	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:05:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:33

Death

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered '0'	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:05:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered '0'	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:05:59

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**Folder:** Adverse Events

**Form:** Adverse Events (3)

**Generated On:** 09 Jun 2021 17:41:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered '0'	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:05:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered empty.	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:05:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:33

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered empty.	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:05:59



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered empty.	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:05:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered empty.	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:05:59

US3432627

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered '0'	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:05:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered '0'	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:05:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered '0'	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:05:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 22:06:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Apr 2021 22:06:07
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Austin Kim (b) (4)	01 Apr 2021 22:06:07
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 22:05:59
User entered empty.	Austin Kim (b) (4)	01 Apr 2021 22:05:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 22:06:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Apr 2021 22:06:07
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Austin Kim (b) (4)	01 Apr 2021 22:06:07
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 22:05:59
User entered empty.	Austin Kim (b) (4)	01 Apr 2021 22:05:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:33

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered 'None (NONE)'	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:05:59



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:33

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered '0'	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:05:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered 'I'	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:05:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered '0'	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:05:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:33

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:05:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:33

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered empty.	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:05:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:41:33

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered empty.	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:05:59

**US3432627**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:41:33**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Apr 2021 22:05:59

**US3432627**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:41:33**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Apr 2021 22:05:59



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:41:33

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:58:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 21:08:37
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	21 Oct 2020 18:23:58

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:41:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 18:26:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 18:26:43
Data point term sent to Coder	System	21 Oct 2020 18:25:40
User entered 'albuterol'	Julia Klopfer (b) (4)	21 Oct 2020 18:25:20

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:41:33**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered 'No (N)'	Julia Klopfer (b) (4)	21 Oct 2020 18:25:20
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:41:33**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered 'asthma'	Julia Klopfer (b) (4)	21 Oct 2020 18:25:20
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:41:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered '1'	Julia Klopfer (b) (4)	21 Oct 2020 18:25:20
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:41:33**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered 'puff (PUFF)'	Julia Klopfer (b) (4)	21 Oct 2020 18:25:20
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:41:33**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered empty.	Julia Klopfer (b) (4)	21 Oct 2020 18:25:20
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:41:33**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered 'as needed (PRN)'	Julia Klopfer (b) (4)	21 Oct 2020 18:25:20
	(b) (4)	



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:41:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 03:35:08
User entered empty.	Julia Klopfer (b) (4) (b) (4)	21 Oct 2020 18:25:20

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:41:33**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Julia Klopfer (b) (4)	21 Oct 2020 18:25:20
	(b) (4)	

US3432627

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:41:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 03:35:08
User entered empty.	Julia Klopfer (b) (4) (b) (4)	21 Oct 2020 18:25:20

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:41:33

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered 'un UNK 2012'	Julia Klopfer (b) (4)	21 Oct 2020 18:25:20
	(b) (4)	

US3432627

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:41:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 03:35:08
User entered '0'	Julia Klopfer (b) (4) (b) (4)	21 Oct 2020 18:25:20

US3432627

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:41:33**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	21 Oct 2020 18:25:20
	(b) (4)	

US3432627

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:41:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 03:35:08
User entered empty.	Julia Klopfer (b) (4) (b) (4)	21 Oct 2020 18:25:20

US3432627

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:41:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered 'No (N)'	Julia Klopfer (b) (4)	21 Oct 2020 18:25:20
	(b) (4)	



**US3432627**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:41:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 18:25:20

US3432627

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:41:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 18:25:20

**US3432627**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:41:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Oct 2020 18:25:20

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
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)	02 Dec 2020 15:44:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Dec 2020 15:44:59
Data point term sent to Coder	System	02 Dec 2020 15:43:50
User entered 'TYLENOL'	Kathleen Garvey (b) (4)	02 Dec 2020 15:43:40

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered 'No (N)'	Kathleen Garvey (b) (4)	02 Dec 2020 15:43:40

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:33

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 08:16:00
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' answered with 'no ae needed' (Site from DM).	Monica Feeley (b) (4)	04 Feb 2021 22:55:57

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:33

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 06:29:45
User entered 'HEADACHE'	Kathleen Garvey (b) (4) (b) (4)	02 Dec 2020 15:43:40

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered '650'	Kathleen Garvey (b) (4)	02 Dec 2020 15:43:40



US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered 'mg (mg)'	Kathleen Garvey (b) (4)	02 Dec 2020 15:43:40

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered empty.	Kathleen Garvey (b) (4)	02 Dec 2020 15:43:40

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered 'twice daily (BID)'	Kathleen Garvey (b) (4)	02 Dec 2020 15:43:40

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered empty.	Kathleen Garvey (b) (4)	02 Dec 2020 15:43:40

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered 'Oral (ORAL)'	Kathleen Garvey (b) (4)	02 Dec 2020 15:43:40

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered empty.	Kathleen Garvey (b) (4)	02 Dec 2020 15:43:40

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered '19 Nov 2020'	Kathleen Garvey (b) (4)	02 Dec 2020 15:43:40

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered '0'	Kathleen Garvey (b) (4)	02 Dec 2020 15:43:40



US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered 'No (N)'	Kathleen Garvey (b) (4)	02 Dec 2020 15:43:40

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered '19 Nov 2020'	Kathleen Garvey (b) (4)	02 Dec 2020 15:43:40

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	02 Dec 2020 15:43:40

US3432627

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:41:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:10
User entered '2'	System	02 Dec 2020 15:43:40

US3432627

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:41:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:10
User entered '1'	System	02 Dec 2020 15:43:40

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:41:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:10
User entered '804 (804)'	System	02 Dec 2020 15:43:40

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:41:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:58:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 13:24:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 13:24:47
Data point term sent to Coder	System	02 Dec 2020 15:44:51
User entered 'OXYCODONE'	Kathleen Garvey (b) (4)	02 Dec 2020 15:44:48

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:41:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:58:42
User entered 'No (N)'	Kathleen Garvey (b) (4)	02 Dec 2020 15:44:48



US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:41:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:58:39
User entered 'PAIN AFTER LEFT INGUINAL HERNIA REPAIR'	Kathleen Garvey (b) (4) (b) (4)	02 Dec 2020 15:44:48

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:41:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:58:37
User entered '5'	Kathleen Garvey (b) (4)	02 Dec 2020 15:44:48

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:41:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:58:35
User entered 'mg (mg)'	Kathleen Garvey (b) (4)	02 Dec 2020 15:44:48

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:41:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:58:33
User entered empty.	Kathleen Garvey (b) (4)	02 Dec 2020 15:44:48

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:41:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:58:32
User entered 'once daily (QD)'	Kathleen Garvey (b) (4)	02 Dec 2020 15:44:48

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:41:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:58:31
User entered empty.	Kathleen Garvey (b) (4)	02 Dec 2020 15:44:48

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:41:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:58:29
User entered 'Oral (ORAL)'	Kathleen Garvey (b) (4)	02 Dec 2020 15:44:48

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:41:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:58:27
User entered empty.	Kathleen Garvey (b) (4)	02 Dec 2020 15:44:48



US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:41:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:58:25
User entered '23 Nov 2020'	Kathleen Garvey (b) (4)	02 Dec 2020 15:44:48

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:41:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:58:24
User entered '0'	Kathleen Garvey (b) (4)	02 Dec 2020 15:44:48

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:41:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:58:22
User entered 'No (N)'	Kathleen Garvey (b) (4)	02 Dec 2020 15:44:48

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:41:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:58:20
User entered '28 Nov 2020'	Kathleen Garvey (b) (4)	02 Dec 2020 15:44:48

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:41:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:58:19
User entered 'No (N)'	Kathleen Garvey (b) (4)	02 Dec 2020 15:44:48

US3432627

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:41:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:16
User entered '1'	System	02 Dec 2020 15:44:48

US3432627

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:41:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:16
User entered '1'	System	02 Dec 2020 15:44:48

US3432627

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:41:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:16
User entered '804 (804)'	System	02 Dec 2020 15:44:48



US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:41:33

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Dec 2020 18:11:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Dec 2020 18:11:45
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:52:07
Data point term sent to Coder	System	04 Dec 2020 18:18:26
User entered 'Celecoxib'	Monica Feeley (b) (4) (b) (4)	04 Dec 2020 18:18:22

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:41:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:52:05
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 18:18:22

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:41:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:52:03
User entered 'pain from hernia repair'	Monica Feeley (b) (4)	04 Dec 2020 18:18:22

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:41:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:52:02
User entered '200'	Monica Feeley (b) (4)	04 Dec 2020 18:18:22

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:41:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:52:00
User entered 'mg (mg)'	Monica Feeley (b) (4)	04 Dec 2020 18:18:22

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:41:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:51:58
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 18:18:22

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:41:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:51:57
User entered 'once (ONCE)'	Monica Feeley (b) (4)	04 Dec 2020 18:18:22

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:41:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:51:55
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 18:18:22



US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:41:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:51:53
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	04 Dec 2020 18:18:22

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:41:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:51:51
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 18:18:22

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:41:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:51:49
User entered '23 Nov 2020'	Monica Feeley (b) (4)	04 Dec 2020 18:18:22

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:41:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:51:48
User entered '0'	Monica Feeley (b) (4)	04 Dec 2020 18:18:22

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:41:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:51:45
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 18:18:22

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:41:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:51:43
User entered '23 Nov 2020'	Monica Feeley (b) (4)	04 Dec 2020 18:18:22

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:41:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:51:41
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 18:18:22

US3432627

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:41:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:29
User entered empty.	System	04 Dec 2020 18:18:22



US3432627

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:41:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:29
User entered empty.	System	04 Dec 2020 18:18:22

US3432627

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:41:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:29
User entered empty.	System	04 Dec 2020 18:18:22

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:41:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:53:28
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)	04 Dec 2020 18:21:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Dec 2020 18:21:02
Data point term sent to Coder	System	04 Dec 2020 18:19:26
User entered 'Tylenol'	Monica Feeley (b) (4)	04 Dec 2020 18:19:25

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:41:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:53:26
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 18:19:25

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:41:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:53:24
User entered 'pain from hernia repair'	Monica Feeley (b) (4)	04 Dec 2020 18:19:25

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:41:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:53:23
User entered '975'	Monica Feeley (b) (4)	04 Dec 2020 18:19:25

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:41:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:53:21
User entered 'mg (mg)'	Monica Feeley (b) (4)	04 Dec 2020 18:19:25

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:41:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:53:18
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 18:19:25



US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:41:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:53:16
User entered 'once (ONCE)'	Monica Feeley (b) (4)	04 Dec 2020 18:19:25

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:41:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:53:13
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 18:19:25

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:41:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:53:11
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	04 Dec 2020 18:19:25

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:41:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:53:07
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 18:19:25

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:41:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:53:05
User entered '23 Nov 2020'	Monica Feeley (b) (4)	04 Dec 2020 18:19:25

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:41:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:53:03
User entered '0'	Monica Feeley (b) (4)	04 Dec 2020 18:19:25

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:41:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:53:02
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 18:19:25

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:41:33

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:53:00
User entered '23 Nov 2020'	Monica Feeley (b) (4)	04 Dec 2020 18:19:25



US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:41:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:52:58
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 18:19:25

US3432627

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:41:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:37
User entered empty.	System	04 Dec 2020 18:19:25

US3432627

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:41:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:37
User entered empty.	System	04 Dec 2020 18:19:25

US3432627

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:41:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:37
User entered empty.	System	04 Dec 2020 18:19:25

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:41:33

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 21:04:14
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)	04 Dec 2020 18:22:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Dec 2020 18:22:39
Data point term sent to Coder	System	04 Dec 2020 18:21:30
User entered 'Tylenol'	Monica Feeley (b) (4)	04 Dec 2020 18:20:40

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:41:33

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 21:04:16
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 18:20:40

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:41:33

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User closed query 'Please add Hernia S/P Inguinal hernia repair to Concomitant procedures in source and EDC, as it was an invasive procedure.' (Site from CRA).	(b) (4), (b) (6)	22 Jan 2021 18:58:04
Query 'Please add Hernia S/P Inguinal hernia repair to Concomitant procedures in source and EDC, as it was an invasive procedure.' answered with 'added' (Site from CRA).	Monica Feeley (b) (4)	22 Jan 2021 18:29:08
User opened query 'Please add Hernia S/P Inguinal hernia repair to Concomitant procedures in source and EDC, as it was an invasive procedure.' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 19:54:47
User closed query 'Per ETRTR, According to AE HERNIA S/P LEFT INGUINAL HERNIA REPAIR, Concomitant procedure was done but no data is entered in Concomitant Procedures page. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 19:54:47
Query 'Per ETRTR, According to AE HERNIA S/P LEFT INGUINAL HERNIA REPAIR, Concomitant procedure was done but no data is entered in Concomitant Procedures page. Please reconcile.' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	07 Jan 2021 15:40:33
User opened query 'Per ETRTR, According to AE HERNIA S/P LEFT INGUINAL HERNIA REPAIR, Concomitant procedure was done but no data is entered in Concomitant Procedures page. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	08 Dec 2020 23:47:09
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 21:04:37
User entered 'Pain from hernia repair'	Monica Feeley (b) (4)	04 Dec 2020 18:20:40

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:41:33

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 21:04:40
User entered '1000'	Monica Feeley (b) (4)	04 Dec 2020 18:20:40



US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:41:33

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 21:04:41
User entered 'mg (mg)'	Monica Feeley (b) (4)	04 Dec 2020 18:20:40

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:41:33

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 21:04:45
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 18:20:40

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:41:33

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 18:58:10
User entered 'other (OTHER)'	Monica Feeley (b) (4)	04 Dec 2020 18:20:40

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:41:33

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 18:58:12
User closed query 'Per source EMR: frequency is every 8hrs for 4 days from 24Nov20 and then 3 times as needed. Please review and edit frequency, stop date and start date as required.' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 19:55:18
Query 'Per source EMR: frequency is every 8hrs for 4 days from 24Nov20 and then 3 times as needed. Please review and edit frequency, stop date and start date as required.' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	07 Jan 2021 15:41:31
User entered 'Q8 HOURS for 4 days then up to 3 times a day' reason for change: Per Query Resolution	Monica Feeley (b) (4)	07 Jan 2021 15:41:27
User opened query 'Per source EMR: frequency is every 8hrs for 4 days from 24Nov20 and then 3 times as needed. Please review and edit frequency, stop date and start date as required.' (Site from CRA).	(b) (4), (b) (6)	04 Dec 2020 21:05:48
User entered 'Q8 hours'	Monica Feeley (b) (4)	04 Dec 2020 18:20:40

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:41:33

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 21:08:21
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	04 Dec 2020 18:20:40

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:41:33

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 21:08:23
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 18:20:40

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:41:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 21:08:24
User entered '24 Nov 2020'	Monica Feeley (b) (4)	04 Dec 2020 18:20:40

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:41:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 21:08:26
User entered '0'	Monica Feeley (b) (4)	04 Dec 2020 18:20:40



US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:41:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:55:38
DataPoint Un-verified.	Kathleen Garvey (b) (4)	09 Dec 2020 19:06:13
User entered 'No (N)' reason for change: New Information	Kathleen Garvey (b) (4)	09 Dec 2020 19:06:13
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 21:08:28
User entered 'Yes (Y)'	Monica Feeley (b) (4)	04 Dec 2020 18:20:40

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:41:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User closed query 'Per DM CLR: Con Med stop date is after the stop date of the AE HERNIA S/P LEFT INGUINAL HERNIA REPAIR. It is not expected that this treatment would continue past the AE. Please review and reconcile Con Med and AE stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 08:16:19
Query 'Per DM CLR: Con Med stop date is after the stop date of the AE HERNIA S/P LEFT INGUINAL HERNIA REPAIR. It is not expected that this treatment would continue past the AE. Please review and reconcile Con Med and AE stop dates as appropriate. ' answered with 'this would definitely continue post surgery.' (Site from DM).	Monica Feeley (b) (4)	04 Feb 2021 22:56:34
User opened query 'Per DM CLR: Con Med stop date is after the stop date of the AE HERNIA S/P LEFT INGUINAL HERNIA REPAIR. It is not expected that this treatment would continue past the AE. Please review and reconcile Con Med and AE stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 06:30:12
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 19:55:40
DataPoint Un-verified.	Kathleen Garvey (b) (4)	09 Dec 2020 19:06:13
User entered '2 Dec 2020' reason for change: Data Entry Error	Kathleen Garvey (b) (4)	09 Dec 2020 19:06:13
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 21:08:29
User entered empty.	Monica Feeley (b) (4)	04 Dec 2020 18:20:40

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:41:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 21:08:31
User entered 'No (N)'	Monica Feeley (b) (4)	04 Dec 2020 18:20:40

US3432627

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:41:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:54
User entered empty.	System	04 Dec 2020 18:20:40

US3432627

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:41:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:54
User entered empty.	System	04 Dec 2020 18:20:40

**US3432627**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:41:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:24:54
User entered empty.	System	04 Dec 2020 18:20:40

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:41:33

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: SECOND-GENERATION CEPHALOSPORINS, PRODUCT: CEFUROXIME - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 09:25:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 09:25:24
User signature succeeded.	Lindsey Baden (b) (4) (b) (4)	04 Apr 2021 21:11:43
Data point term sent to Coder	System	01 Apr 2021 22:07:13
User entered 'Cefuroxime'	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:06:57

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:41:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
User entered 'No (N)'	Austin Kim (b) (4)	01 Apr 2021 22:06:57
	(b) (4)	



US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:41:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
User entered 'UTI'	Austin Kim (b) (4)	01 Apr 2021 22:06:57
	(b) (4)	

US3432627

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:41:33**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
User entered '500'	Austin Kim (b) (4)	01 Apr 2021 22:06:57
	(b) (4)	

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:41:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered 'mg (mg)'	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:06:57

US3432627

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:41:33**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered empty.	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:06:57

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:41:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered 'twice daily (BID)'	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:06:57

US3432627

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:41:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered empty.	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:06:57

US3432627

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:41:33**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered 'Oral (ORAL)'	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:06:57

US3432627

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:41:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered empty.	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:06:57



US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:41:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
User entered '30 Mar 2021'	Austin Kim (b) (4)	01 Apr 2021 22:06:57
	(b) (4)	

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:41:33

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
User entered '0'	Austin Kim (b) (4)	01 Apr 2021 22:06:57
	(b) (4)	

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:41:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
User entered 'Yes (Y)' reason for change: Data Entry Error	Austin Kim (b) (4)	01 Apr 2021 22:09:24
User entered 'No (N)' reason for change: Data Entry Error	Austin Kim (b) (4)	01 Apr 2021 22:09:13
User entered 'Yes (Y)'	Austin Kim (b) (4)	01 Apr 2021 22:06:57

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:41:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	01 Apr 2021 22:09:24
User entered empty; reason for change Data Entry Error	Austin Kim (b) (4)	01 Apr 2021 22:09:24
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	01 Apr 2021 22:09:13
User entered '06 Apr 2021' reason for change: Data Entry Error	Austin Kim (b) (4)	01 Apr 2021 22:09:13
User entered empty.	Austin Kim (b) (4)	01 Apr 2021 22:06:57

US3432627

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:41:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered 'No (N)'	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:06:57

**US3432627**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:41:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Apr 2021 22:06:57

US3432627

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:41:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 22:06:57

US3432627

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:41:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Apr 2021 22:06:57



US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:41:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 22:12:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Apr 2021 22:12:15
Data point term sent to Coder	System	01 Apr 2021 22:11:16
User entered 'vitamin D'	Austin Kim (b) (4)	01 Apr 2021 22:10:18
	(b) (4)	

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:41:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered 'No (N)'	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:10:18

US3432627

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:41:33**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
User entered 'general health'	Austin Kim (b) (4)	01 Apr 2021 22:10:18
	(b) (4)	

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:41:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
User entered '50,000'	Austin Kim (b) (4)	01 Apr 2021 22:10:18
	(b) (4)	

US3432627

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:41:33**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered 'Other (OTHER)'	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:10:18

US3432627

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:41:33**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered 'units'	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:10:18

US3432627

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:41:33**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered 'every week (QS)'	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:10:18

US3432627

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:41:33**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered empty.	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:10:18



US3432627

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:41:33**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered 'Oral (ORAL)'	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:10:18

US3432627

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:41:33**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered empty.	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:10:18

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:41:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
User entered '30 Mar 2021'	Austin Kim (b) (4)	01 Apr 2021 22:10:18
	(b) (4)	

US3432627

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:41:33**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
User entered '0'	Austin Kim (b) (4)	01 Apr 2021 22:10:18
	(b) (4)	

US3432627

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:41:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
User entered 'Yes (Y)'	Austin Kim (b) (4)	01 Apr 2021 22:10:18
	(b) (4)	

US3432627

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:41:33**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	04 Apr 2021 21:11:43
User entered empty.	Austin Kim (b) (4) (b) (4)	01 Apr 2021 22:10:18

US3432627

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:41:33**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:11:43
User entered 'No (N)'	Austin Kim (b) (4)	01 Apr 2021 22:10:18
	(b) (4)	

**US3432627**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:41:33**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 22:10:18



**US3432627**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:41:33**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 22:10:18

US3432627

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:41:33**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	01 Apr 2021 22:10:18

US3432627

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:41:33

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:58:26
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 18:57:35
User entered 'Yes (Y)'	Monica Feeley (b) (4)	22 Jan 2021 18:26:43

US3432627

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:41:33

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 18:57:50
User entered '23 Nov 2020'	Monica Feeley (b) (4)	22 Jan 2021 18:28:27
	(b) (4)	

US3432627

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:41:33

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 18:57:50
User entered 'Hernia Repair'	Monica Feeley (b) (4)	22 Jan 2021 18:28:27
	(b) (4)	

US3432627

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:41:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 18:57:50
User entered 'Adverse Event (AE)'	Monica Feeley (b) (4)	22 Jan 2021 18:28:27
	(b) (4)	

US3432627

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 17:41:33**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 18:57:50
User entered empty.	Monica Feeley (b) (4)	22 Jan 2021 18:28:27
	(b) (4)	

US3432627

Folder: SAE USA-US078-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:21
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 13:03:56
User entered 'USA-US078-2020-MRNA-1273-P301000014'	System	25 Nov 2020 13:03:38



US3432627

Folder: SAE USA-US078-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:21
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 13:03:56
User entered 'Yes (Y)'	System	25 Nov 2020 13:03:38

US3432627

Folder: SAE USA-US078-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:33

Death

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:21
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 13:03:56
User entered 'No (N)'	System	25 Nov 2020 13:03:38

US3432627

Folder: SAE USA-US078-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:21
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 13:03:56
User entered 'No (N)'	System	25 Nov 2020 13:03:38

US3432627

Folder: SAE USA-US078-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:21
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 13:03:56
User entered 'Yes (Y)'	System	25 Nov 2020 13:03:38

US3432627

Folder: SAE USA-US078-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:21
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 13:03:56
User entered 'No (N)'	System	25 Nov 2020 13:03:38

US3432627

Folder: SAE USA-US078-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:21
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 13:03:56
User entered 'No (N)'	System	25 Nov 2020 13:03:38

US3432627

Folder: SAE USA-US078-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:21
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 13:03:56
User entered 'No (N)'	System	25 Nov 2020 13:03:38

US3432627

Folder: SAE USA-US078-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:21
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 13:03:56
User entered 'Lindsey'	System	25 Nov 2020 13:03:38



US3432627

Folder: SAE USA-US078-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:21
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 13:03:56
User entered 'Baden'	System	25 Nov 2020 13:03:38

US3432627

Folder: SAE USA-US078-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:33

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:21
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 13:03:56
User entered 'MA'	System	25 Nov 2020 13:03:38

US3432627

Folder: SAE USA-US078-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:21
User entered 'US'	System	25 Nov 2020 13:04:01

US3432627

Folder: SAE USA-US078-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered 'I'	System	25 Nov 2020 13:04:01

US3432627

Folder: SAE USA-US078-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:21
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 13:03:56
User entered 'USA-US078-2020-MRNA-1273-P301000014'	System	25 Nov 2020 13:03:38

US3432627

Folder: SAE USA-US078-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:21
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 13:03:56
User entered 'Yes (Y)'	System	25 Nov 2020 13:03:38

US3432627

Folder: SAE USA-US078-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:33

Death

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:21
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 13:03:56
User entered 'No (N)'	System	25 Nov 2020 13:03:38

US3432627

Folder: SAE USA-US078-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:21
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 13:03:56
User entered 'No (N)'	System	25 Nov 2020 13:03:38



US3432627

Folder: SAE USA-US078-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:21
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 13:03:56
User entered 'Yes (Y)'	System	25 Nov 2020 13:03:38

US3432627

Folder: SAE USA-US078-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:21
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 13:03:56
User entered 'No (N)'	System	25 Nov 2020 13:03:38

US3432627

Folder: SAE USA-US078-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:21
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 13:03:56
User entered 'No (N)'	System	25 Nov 2020 13:03:38

US3432627

Folder: SAE USA-US078-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:21
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 13:03:56
User entered 'No (N)'	System	25 Nov 2020 13:03:38

US3432627

Folder: SAE USA-US078-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:21
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 13:03:56
User entered 'Lindsey'	System	25 Nov 2020 13:03:38

US3432627

Folder: SAE USA-US078-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:21
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 13:03:56
User entered 'Baden'	System	25 Nov 2020 13:03:38

US3432627

Folder: SAE USA-US078-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:33

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:21
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 13:03:56
User entered 'MA'	System	25 Nov 2020 13:03:38

US3432627

Folder: SAE USA-US078-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:21
User entered 'US'	System	25 Nov 2020 13:04:01



US3432627

Folder: SAE USA-US078-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:41:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
User entered 'I'	System	25 Nov 2020 13:04:01

US3432627

Folder: SAE USA-US078-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:41:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:21
User entered '25/Nov/2020 13:04'	System	25 Nov 2020 13:04:01

US3432627

Folder: SAE USA-US078-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:41:33

**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 03:35:08
DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 20:36:21
User entered 'I'	(b) (4), (b) (6)	25 Nov 2020 13:04:01