

US3432641 (Prod: Brigham and Womens Hospital)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:40:32

All time stamps listed in this document are displayed in GMT

US3432641

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

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[Participant ID](#)

US3432641

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

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US3432641

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3432641

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

Date of Birth (MMM yyyy)	(b) (6) 1979
Age	40
Age Units	YEARS
Age (Derived)	40
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	True
If race is Other, specify	HISPANIC/LATINO
Unknown	False
Not reported	False

US3432641

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

Date of Informed Consent (dd MMM yyyy) 22 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

US3432641

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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US3432641

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

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Were any significant conditions reported?

Yes ☒

No ☐

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US3432641

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

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



US3432641

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

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

US3432641

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

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

US3432641

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 OCT 2020
Time of assessment (00:00-23:59)	11:32 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 11:32
Height (xxx.x)	154 cm
Weight (xxx.x)	92.3 kg
BMI (xxx.x)	38.91887 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432641

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 OCT 2020

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

US3432641

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

Date of assessment (dd MMM yyyy) 22 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

US3432641

Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

Was the pregnancy test performed? Yes ☒  
No ☐

Date of test (dd MMM yyyy) 22 OCT 2020

Test performed Urine ☒  
Serum ☐

Result Positive ☐  
Negative ☒

Was FSH sample collected? Yes ☐  
No ☒

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

US3432641

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

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**Occupational Risk**

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**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)**

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**No Risk Identified** False

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

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US3432641

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

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



US3432641

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 03:38:20

Generated On: 11 Aug 2021 22:40:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3432641

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

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

What was the participant's randomization number? 117784

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 ☒

US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 03:38:20

Generated On: 11 Aug 2021 22:40:32

Height	ND - Not Done
Weight	ND - Not Done

US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 03:38:20

Generated On: 11 Aug 2021 22:40:32

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 OCT 2020
Time of assessment (00:00-23:59)	13:32 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 13:32
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	58 mmHg
Diastolic Blood Pressure units	MMHG

US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 03:38:20

Generated On: 11 Aug 2021 22:40:32

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 OCT 2020
Time of assessment (00:00-23:59)	15:13 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 15:13
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	IR
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)	69 mmHg
Diastolic Blood Pressure units	MMHG

US3432641

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

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.*

US3432641

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

Was the pregnancy test performed? Yes ☐  
No ☒

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

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☒

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

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

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

US3432641

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 14:43 (24 HR)

Treatment Date and Time (derived) 22 OCT 2020 14:43

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



US3432641

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 OCT 2020

Collection time (00:00-23:59)

13:39 (24 HR)

Collection date and time (derived)

22 OCT 2020 13:39

US3432641

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

Collection date (dd MMM yyyy)			22 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:45	22 OCT 2020 13:45
Nasopharyngeal Swab 2	No		

US3432641

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

**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

22 OCT 2020 15:16

PC Open Date & Time

22 OCT 2020 15:03

PC Close Date & Time

22 OCT 2020 17:33

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp 22 OCT 2020 19:08

PC Open Date & Time 22 OCT 2020 18:28

PC Close Date & Time 23 OCT 2020 11:59

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

23 OCT 2020 21:58

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:40:32

**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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 OCT 2020 16:30

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

25 OCT 2020 14:54

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59



US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

26 OCT 2020 18:10

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

28 OCT 2020 08:07

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 OCT 2020 08:34

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

22 OCT 2020 15:17

PC Open Date & Time

22 OCT 2020 15:03

PC Close Date & Time

22 OCT 2020 17:33

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

**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

22 OCT 2020 19:09

PC Open Date & Time

22 OCT 2020 18:28

PC Close Date & Time

23 OCT 2020 11:59

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 OCT 2020 21:59

PC Open Date & Time

23 OCT 2020 12:00

PC Close Date & Time

24 OCT 2020 11:59

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:40:32

**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

24 OCT 2020 16:30

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:40:32

TIMEPOINT	DAY 4
Please record - <b>PAIN AT INJECTION SITE.</b>	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any <b>REDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any <b>SWELLING/HARDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - <b>UNDERARM GLAND SWELLING OR TENDERNESS.</b>	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	25 OCT 2020 14:54
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59



US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

26 OCT 2020 18:10

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

28 OCT 2020 08:07

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 OCT 2020 08:34

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

**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 ☐

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

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

No ☒

Yes ☐

PC Time stamp	22 OCT 2020 15:19
PC Open Date & Time	22 OCT 2020 15:03
PC Close Date & Time	22 OCT 2020 17:33

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

**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 ☐

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

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

No ☒

Yes ☐

PC Time stamp	22 OCT 2020 19:09
PC Open Date & Time	22 OCT 2020 18:28
PC Close Date & Time	23 OCT 2020 11:59

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:40:32

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 ☒

PRODUCTION RELEASE (v12.003

47 of 1713

EAB) (1725)



US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:40:32

		Yes <input type="checkbox"/>
PC Time stamp	23 OCT 2020 22:00	
PC Open Date & Time	23 OCT 2020 12:00	
PC Close Date & Time	24 OCT 2020 11:59	

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:40:32

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

49 of 1713

EAB) (1725)

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:40:32

Yes <input type="checkbox"/>	
PC Time stamp	24 OCT 2020 16:30
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

51 of 1713

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:40:32

Yes <input type="checkbox"/>	
PC Time stamp	25 OCT 2020 14:55
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:40:32

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

53 of 1713

EAB) (1725)

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:40:32

Yes <input type="checkbox"/>	
PC Time stamp	26 OCT 2020 18:10
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:40:32

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 1713



US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:40:32

Yes <input type="checkbox"/>	
PC Time stamp	28 OCT 2020 08:07
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:40:32

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

57 of 1713

EAB) (1725)

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:40:32

Yes <input type="checkbox"/>	
PC Time stamp	29 OCT 2020 08:34
PC Open Date & Time	28 OCT 2020 12:00
PC Close Date & Time	29 OCT 2020 11:59

US3432641

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3432641

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432641

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3432641

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432641

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3432641

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432641

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 03:38:20

Generated On: 11 Aug 2021 22:40:32

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

Visit date (dd MMM yyyy)	25 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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US3432641

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 03:38:20

Generated On: 11 Aug 2021 22:40:32

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 NOV 2020
Time of assessment (00:00-23:59)	13:26 (24 HR)
Vital Signs Date and Time (derived)	25 NOV 2020 13:26
Temperature (xxx.x)	036.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	085 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	071 mmHg
Diastolic Blood Pressure units	MMHG

US3432641

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 03:38:20

Generated On: 11 Aug 2021 22:40:32

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)	25 NOV 2020
Time of assessment (00:00-23:59)	14:49 (24 HR)
Vital Signs Date and Time (derived)	25 NOV 2020 14:49
Temperature (xxx.x)	036.9 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	076 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	012 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	072 mmHg
Diastolic Blood Pressure units	MMHG

US3432641

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 03:38:20

Generated On: 11 Aug 2021 22:40:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 NOV 2020

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

US3432641

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 03:38:20

Generated On: 11 Aug 2021 22:40:32

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

US3432641

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 03:38:20

Generated On: 11 Aug 2021 22:40:32

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 14:19 (24 HR)

Treatment Date and Time (derived) 25 NOV 2020 14:19

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

US3432641

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 03:38:20

Generated On: 11 Aug 2021 22:40:32

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

Collection date (dd MMM yyyy)	25 NOV 2020
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Collection time (00:00-23:59)	13:52 (24 HR)
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Collection date and time (derived)	25 NOV 2020 13:52
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US3432641

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 03:38:20

Generated On: 11 Aug 2021 22:40:32

Collection date (dd MMM yyyy)			25 NOV 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:55	25 NOV 2020 13:55
Nasopharyngeal Swab 2	No		

US3432641

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:38:20

Generated On: 11 Aug 2021 22:40:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 NOV 2020 14:54

PC Open Date & Time

25 NOV 2020 14:39

PC Close Date & Time

25 NOV 2020 17:09

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

**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 98.2 °F

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

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

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

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

PC Time Stamp 25 NOV 2020 19:02

PC Open Date & Time 25 NOV 2020 18:04

PC Close Date & Time 26 NOV 2020 11:59

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:40:32

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.5 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	27 NOV 2020 07:27
PC Open Date & Time	26 NOV 2020 12:00
PC Close Date & Time	27 NOV 2020 11:59

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:40:32

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**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

98.5 °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

28 NOV 2020 07:39

PC Open Date & Time

27 NOV 2020 12:00

PC Close Date & Time

28 NOV 2020 11:59

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 NOV 2020 09:14

PC Open Date & Time

28 NOV 2020 12:00

PC Close Date & Time

29 NOV 2020 11:59

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

30 NOV 2020 09:35

PC Open Date & Time

29 NOV 2020 12:00

PC Close Date & Time

30 NOV 2020 11:59



US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 DEC 2020 10:12

PC Open Date & Time

30 NOV 2020 12:00

PC Close Date & Time

01 DEC 2020 11:59

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

02 DEC 2020 10:11

PC Open Date & Time

01 DEC 2020 12:00

PC Close Date & Time

02 DEC 2020 11:59

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

**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

25 NOV 2020 14:55

PC Open Date & Time

25 NOV 2020 14:39

PC Close Date & Time

25 NOV 2020 17:09

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 NOV 2020 19:04

PC Open Date & Time

25 NOV 2020 18:04

PC Close Date & Time

26 NOV 2020 11:59

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:40:32

**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

27 NOV 2020 07:27

PC Open Date & Time

26 NOV 2020 12:00

PC Close Date & Time

27 NOV 2020 11:59

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

28 NOV 2020 07:39

PC Open Date & Time

27 NOV 2020 12:00

PC Close Date & Time

28 NOV 2020 11:59

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:40:32

TIMEPOINT	DAY 4
Please record - <b>PAIN AT INJECTION SITE.</b>	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any <b>REDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any <b>SWELLING/HARDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - <b>UNDERARM GLAND SWELLING OR TENDERNESS.</b>	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	29 NOV 2020 09:15
PC Open Date & Time	28 NOV 2020 12:00
PC Close Date & Time	29 NOV 2020 11:59

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

30 NOV 2020 09:35

PC Open Date & Time

29 NOV 2020 12:00

PC Close Date & Time

30 NOV 2020 11:59



US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:40:32

**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

01 DEC 2020 10:12

PC Open Date & Time

30 NOV 2020 12:00

PC Close Date & Time

01 DEC 2020 11:59

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 DEC 2020 10:11

PC Open Date & Time

01 DEC 2020 12:00

PC Close Date & Time

02 DEC 2020 11:59

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

**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 ☐

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

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

No ☒

Yes ☐

PC Time stamp	25 NOV 2020 14:55
PC Open Date & Time	25 NOV 2020 14:39
PC Close Date & Time	25 NOV 2020 17:09

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

**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 ☐

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

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

No ☒

Yes ☐

PC Time stamp	25 NOV 2020 19:04
PC Open Date & Time	25 NOV 2020 18:04
PC Close Date & Time	26 NOV 2020 11:59

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:40:32

**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 ☒

PRODUCTION RELEASE (v12.003

94 of 1713

EAB) (1725)

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:40:32

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



US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:40:32

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

96 of 1713

EAB) (1725)

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:40:32

Yes <input type="checkbox"/>	
PC Time stamp	28 NOV 2020 07:40
PC Open Date & Time	27 NOV 2020 12:00
PC Close Date & Time	28 NOV 2020 11:59

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:40:32

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

98 of 1713

EAB) (1725)

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:40:32

Yes <input type="checkbox"/>	
PC Time stamp	29 NOV 2020 09:15
PC Open Date & Time	28 NOV 2020 12:00
PC Close Date & Time	29 NOV 2020 11:59

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:40:32

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

100 of 1713

EAB) (1725)

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:40:32

Yes <input type="checkbox"/>	
PC Time stamp	30 NOV 2020 09:36
PC Open Date & Time	29 NOV 2020 12:00
PC Close Date & Time	30 NOV 2020 11:59

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:40:32

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

102 of 1713

EAB) (1725)

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:40:32

Yes <input type="checkbox"/>	
PC Time stamp	01 DEC 2020 10:12
PC Open Date & Time	30 NOV 2020 12:00
PC Close Date & Time	01 DEC 2020 11:59



US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:40:32

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

104 of 1713

EAB) (1725)

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:40:32

Yes <input type="checkbox"/>	
PC Time stamp	02 DEC 2020 10:11
PC Open Date & Time	01 DEC 2020 12:00
PC Close Date & Time	02 DEC 2020 11:59

US3432641

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

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*

US3432641

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432641

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3432641

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432641

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3432641

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3432641

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 03:38:33

Generated On: 11 Aug 2021 22:40:32

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

Visit date (dd MMM yyyy)	08 JAN 2021
--------------------------	-------------

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

Folder OID	VISIT3
------------	--------

US3432641

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 03:38:33

Generated On: 11 Aug 2021 22:40:32

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 JAN 2021
Time of assessment (00:00-23:59)	10:42 (24 HR)
Vital Signs Date and Time (derived)	08 JAN 2021 10:42
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432641

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 03:38:20

Generated On: 11 Aug 2021 22:40:32

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.*

US3432641

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 04 Apr 2021 21:10:02

Generated On: 11 Aug 2021 22:40:32

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

Collection date (dd MMM yyyy)	08 JAN 2021
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Collection time (00:00-23:59)	11:00 (24 HR)
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Collection date and time (derived)	08 JAN 2021 11:00
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US3432641

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:38:20

Generated On: 11 Aug 2021 22:40:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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	19 DEC 2020 17:17:14
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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 <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	27 DEC 2020 17:52:29
Patient Cloud Open Date & Time	26 DEC 2020 00:01
Patient Cloud Close Date & Time	30 DEC 2020 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 JAN 2021 16:07:56
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59



US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 JAN 2021 17:59:40
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 JAN 2021 12:15:44

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 JAN 2021 13:10:28

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

**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

02 FEB 2021 17:59:20

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 FEB 2021 18:10:53
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 FEB 2021 08:15:06

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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	20 FEB 2021 14:56:09
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

**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

27 FEB 2021 00:03:32

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59



US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

**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

06 MAR 2021 20:16:55

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 MAR 2021 08:00:52

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

**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

20 MAR 2021 09:18:15

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 MAR 2021 09:34:01

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

<b>TIMEPOINT</b>	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 APR 2021 16:45:32
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 APR 2021 07:53:45

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 16:09:19

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

**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

24 APR 2021 08:39:17

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59



US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	01 MAY 2021 20:47:56
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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 <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"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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15 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2021 23:59

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US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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[Patient Cloud Open Date & Time](#)

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22 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2021 23:59

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US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

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09 JUN 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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19 JUN 2021 00:01

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23 JUN 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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"/>



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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26 JUN 2021 00:01

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30 JUN 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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="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"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

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21 JUL 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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24 JUL 2021 00:01

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28 JUL 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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31 JUL 2021 00:01

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04 AUG 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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14 AUG 2021 00:01

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18 AUG 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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"/>



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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21 AUG 2021 00:01

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25 AUG 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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[Patient Cloud Open Date & Time](#)

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11 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 SEP 2021 23:59

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US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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="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"/>



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

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US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

**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 ☐

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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"/>



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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 <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"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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 <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"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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 <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"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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="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"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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"/>



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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="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"/>



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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05 FEB 2022 00:01

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09 FEB 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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12 FEB 2022 00:01

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16 FEB 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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19 FEB 2022 00:01

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23 FEB 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

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02 MAR 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

**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 ☐



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**Form: Safety Follow Up Diary**

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

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

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US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

**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 ☐

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

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16 MAR 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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19 MAR 2022 00:01

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23 MAR 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

TIMEPOINT	DAY 523
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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26 MAR 2022 00:01

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30 MAR 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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"/>



**US3432641**

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

**Form: Safety Follow Up Diary**

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

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

Date and time of submission

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02 APR 2022 00:01

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06 APR 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

**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 ☐

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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13 APR 2022 23:59

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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 <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"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

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27 APR 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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 <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"/>



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

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04 MAY 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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

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 ☐

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

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11 MAY 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

14 MAY 2022 00:01

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18 MAY 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

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25 MAY 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

**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 ☐



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

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01 JUN 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

**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 ☐

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

04 JUN 2022 00:01

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08 JUN 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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11 JUN 2022 00:01

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15 JUN 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

18 JUN 2022 00:01

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22 JUN 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

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29 JUN 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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02 JUL 2022 00:01

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06 JUL 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

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13 JUL 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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16 JUL 2022 00:01

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20 JUL 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

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27 JUL 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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03 AUG 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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10 AUG 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

**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 ☐

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

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17 AUG 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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"/>



**US3432641**

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

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

Date and time of submission

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24 AUG 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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 <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"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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27 AUG 2022 00:01

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31 AUG 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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07 SEP 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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14 SEP 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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"/>



**US3432641**

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

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

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

Date and time of submission

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17 SEP 2022 00:01

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21 SEP 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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28 SEP 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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05 OCT 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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"/>



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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="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"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

**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 ☐

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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 <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"/>



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 DEC 2022 23:59

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

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"/>

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2022 23:59

US3432641

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:40:32

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 12:26:34

US3432641

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3432641

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3432641

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 21:10:02

Generated On: 11 Aug 2021 22:40:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 FEB 2021

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

CALLED PT ON 2/24 @ 16:36,  
AND 2/25 @ 12:31 . PT WAS NOT  
REACHED

*If Contact Not Made, please provide Comments*

US3432641

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 21:10:02

Generated On: 11 Aug 2021 22:40:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432641

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 25 Apr 2021 11:31:27

Generated On: 11 Aug 2021 22:40:32

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 MAR 2021

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

Comments CONTACTED 22MAR2021, NO  
ANSWER. LVM  
If Contact Not Made, please provide Comments CONTACTED 25MAR2021, NO  
ANSWER. LVM.

US3432641

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 25 Apr 2021 11:31:27

Generated On: 11 Aug 2021 22:40:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432641

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 25 Apr 2021 11:31:27

Generated On: 11 Aug 2021 22:40:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3432641

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 25 Apr 2021 11:31:27

Generated On: 11 Aug 2021 22:40:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3432641**

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

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:40:32**

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 \_\_\_\_\_

US3432641

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:32

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)	



US3432641

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:40:32

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.*

US3432641

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:32

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)	_____

US3432641

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:32

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3432641

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:40:32

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"/>

US3432641

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:40:32

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3432641

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

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

Visit date (dd MMM yyyy)	08 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
------------	---------------

US3432641

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

Form: Unblinding

Data signed: (b) (4) 04 Apr 2021 21:10:02

Generated On: 11 Aug 2021 22:40:32

Date of updated informed consent (dd MMM yyyy) 08 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 08 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_

US3432641

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

08 JAN 2021

Collection time (00:00-23:59)

11:00 (24 HR)

Collection date and time (derived)

08 JAN 2021 11:00



US3432641

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

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

Collection date (dd MMM yyyy)	08 JAN 2021
-------------------------------	-------------

Collection time (00:00 - 23:59)	11:10
---------------------------------	-------

Collection Date and Time (derived)	08 JAN 2021 11:10
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US3432641

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3432641

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 25 Apr 2021 11:31:27

Generated On: 11 Aug 2021 22:40:32

AEID	
Adverse event	DYSPEPSIA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	25 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)	27 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

330 of 1713

US3432641

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 25 Apr 2021 11:31:27

Generated On: 11 Aug 2021 22:40:32

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

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 03:38:19

Generated On: 11 Aug 2021 22:40:32

---

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

Yes ☒

No ☐

---

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

---

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 04 Apr 2021 21:10:01

Generated On: 11 Aug 2021 22:40:32

Name of Medication CLARITIN

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

333 of 1713

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 04 Apr 2021 21:10:01

Generated On: 11 Aug 2021 22:40:32

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 04 Apr 2021 21:10:01

Generated On: 11 Aug 2021 22:40:32

Name of Medication ALBUTEROL

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

335 of 1713



US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 04 Apr 2021 21:10:01

Generated On: 11 Aug 2021 22:40:32

	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 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 04 Apr 2021 21:10:01

Generated On: 11 Aug 2021 22:40:32

Name of Medication ALEVE

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

337 of 1713

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 04 Apr 2021 21:10:01

Generated On: 11 Aug 2021 22:40:32

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 04 Apr 2021 21:10:01

Generated On: 11 Aug 2021 22:40:32

Name of Medication AUROVELA

Prophylaxis Yes ☒  
No ☐

Indication BIRTH CONTROL

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

339 of 1713

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 04 Apr 2021 21:10:01

Generated On: 11 Aug 2021 22:40:32

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

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 04 Apr 2021 21:10:01

Generated On: 11 Aug 2021 22:40:32

Name of Medication MOTRIN

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

341 of 1713

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 04 Apr 2021 21:10:01

Generated On: 11 Aug 2021 22:40:32

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 04 Apr 2021 21:10:01

Generated On: 11 Aug 2021 22:40:32

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication INJECTION SITE PAIN AND  
MUSCLE ACHES

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

343 of 1713



US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 04 Apr 2021 21:10:01

Generated On: 11 Aug 2021 22:40:32

	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)	25 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)	26 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"/>

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 04 Apr 2021 21:10:01

Generated On: 11 Aug 2021 22:40:32

Name of Medication PRILOSEC

Prophylaxis Yes ☐  
No ☒

Indication DYSPEPSIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

345 of 1713

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 04 Apr 2021 21:10:01

Generated On: 11 Aug 2021 22:40:32

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 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) 27 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"/>

US3432641

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 04 Apr 2021 21:10:02

Generated On: 11 Aug 2021 22:40:32

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3432641

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:40:32

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

US3432641

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:40:32

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 ☐

Audit

US3432641 (Prod: Brigham and Womens Hospital)

**US3432641**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 22:40:32**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'US3432641'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Oct 2020 17:33:26



US3432641

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:40:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	22 Oct 2020 18:53:42

US3432641

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '22 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Oct 2020 17:33:27

US3432641

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:40:32

[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 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Clinic (Clinic)'	Bruce Bausk (b) (4)	22 Oct 2020 18:53:42

**US3432641**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:40:32**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User entered 'SCRN'	System	22 Oct 2020 18:53:42

US3432641

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:40:32

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
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 1979. Please clarify the subject's Year of Birth and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:28:08
User closed query 'Per GCL Lab Reconciliation: Swab Visit 1 Day 1 and Visit 2 Day 29: Year of Birth (1979) recorded on this form. However Sex and Year of birth is missing in PPD Central lab. Please reconcile the correct date and update if confirmed. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 12:28:06
Query 'Per GCL Lab Reconciliation: Swab Visit 1 Day 1 and Visit 2 Day 29: Year of Birth (1979) recorded on this form. However Sex and Year of birth is missing in PPD Central lab. Please reconcile the correct date and update if confirmed. Else clarify, thank you.' answered with 'birth year on form - it is 1979' (Site from DM).	Phoebe Cunningham (b) (4)	06 Nov 2020 15:24:54
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 1979. Please clarify the subject's Year of Birth and update as appropriate.' answered with 'birth year on form. It is 1979' (Site from DM).	Phoebe Cunningham (b) (4)	06 Nov 2020 15:24:33
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 1979. Please clarify the subject's Year of Birth and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 18:21:22

US3432641

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:40:32

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Swab Visit 1 Day 1 and Visit 2 Day 29: Year of Birth (1979) recorded on this form. However Sex and Year of birth is missing in PPD Central lab. Please reconcile the correct date and update if confirmed. Else clarify, thank you. ' (Site from DM). User entered (b) (6) '1979'	(b) (4), (b) (6)   RWS_ENDPOINT ENDPOINT (b) (4)	30 Oct 2020 06:21:21   22 Oct 2020 17:33:28

US3432641

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:40:32

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '40'	Phoebe Cunningham (b) (4)	06 Nov 2020 15:25:23

US3432641

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:40:32

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User entered 'YEARS'	System	06 Nov 2020 15:25:23



US3432641

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:40:32

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User entered '40'	System	22 Oct 2020 18:53:55

US3432641

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:40:32

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User closed query 'Per CDM: Please complete all required data on this form.' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 13:58:01
Query 'Per CDM: Please complete all required data on this form.' answered with 'updated' (Site from DM).	Jun Bai Park Chang (b) (4)	11 Nov 2020 16:54:33
User entered 'Female (F)'	Phoebe Cunningham (b) (4)	06 Nov 2020 15:25:23
User opened query 'Per CDM: Please complete all required data on this form.' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 06:22:04

US3432641

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:40:32

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Phoebe Cunningham (b) (4)	06 Nov 2020 15:25:23

US3432641

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:40:32

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '0'	Phoebe Cunningham (b) (4)	06 Nov 2020 15:25:23

US3432641

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:40:32

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '0'	Phoebe Cunningham (b) (4)	06 Nov 2020 15:25:23

US3432641

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:40:32

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '0'	Phoebe Cunningham (b) (4)	06 Nov 2020 15:25:23

US3432641

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:40:32

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '0'	Phoebe Cunningham (b) (4)	06 Nov 2020 15:25:23

US3432641

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:40:32

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '0'	Phoebe Cunningham (b) (4)	06 Nov 2020 15:25:23



US3432641

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:40:32

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'l'	Phoebe Cunningham (b) (4)	06 Nov 2020 15:25:23

US3432641

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:40:32

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'hispanic/latino'	Phoebe Cunningham (b) (4)	06 Nov 2020 15:25:23

US3432641

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:40:32

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '0'	Phoebe Cunningham (b) (4)	06 Nov 2020 15:25:23

US3432641

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:40:32

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '0'	Phoebe Cunningham (b) (4)	06 Nov 2020 15:25:23

US3432641

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:40:32

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '22 Oct 2020'	Bruce Bausk (b) (4)	22 Oct 2020 18:53:55

US3432641

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User entered 'Oct 2020'	System	22 Oct 2020 18:53:55

US3432641

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User entered '2020'	System	22 Oct 2020 18:53:55

US3432641

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:40:32

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Amendment 4 (4)'	Bruce Bausk (b) (4)	22 Oct 2020 18:53:55



US3432641

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	22 Oct 2020 18:53:55

US3432641

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:40:32

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	Bruce Bausk (b) (4)	22 Oct 2020 18:53:55

US3432641

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:40:32

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	Bruce Bausk (b) (4)	22 Oct 2020 18:53:55

US3432641

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:40:32

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'No (N)'	Bruce Bausk (b) (4)	22 Oct 2020 18:53:55

US3432641

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:40:32

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	22 Oct 2020 17:33:27

US3432641

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:40:32

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User entered 'l'	System	22 Oct 2020 18:53:58

US3432641

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	22 Oct 2020 18:53:58

US3432641

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:40:32

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	23 Oct 2020 11:29:26



US3432641

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:40:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 11:32:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 11:32:38
Data point term sent to Coder	System	23 Oct 2020 11:31:29
User entered 'seasonal allergies'	Bruce Bausk (b) (4)	23 Oct 2020 11:30:39

US3432641

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'un UNK 2015'	Bruce Bausk (b) (4)	23 Oct 2020 11:30:39

US3432641

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:40:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '0'	Bruce Bausk (b) (4)	23 Oct 2020 11:30:39

US3432641

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:40:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	23 Oct 2020 11:30:39

US3432641

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	Bruce Bausk (b) (4)	23 Oct 2020 11:30:39

US3432641

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:40:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '0'	Bruce Bausk (b) (4)	23 Oct 2020 11:30:39

US3432641

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User entered 'Jan 2015'	System	23 Oct 2020 11:30:39

US3432641

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:40:32

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User entered '2015'	System	23 Oct 2020 11:30:39



US3432641

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User entered empty.	System	23 Oct 2020 11:30:39

US3432641

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User entered empty.	System	23 Oct 2020 11:30:39

US3432641

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:40:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Intermittent headache - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 11:37:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 11:37:25
Data point term sent to Coder	System	23 Oct 2020 11:36:34
User entered 'intermittent headaches'	Bruce Bausk (b) (4)	23 Oct 2020 11:36:13

US3432641

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'un UNK 2000'	Bruce Bausk (b) (4)	23 Oct 2020 11:36:13

US3432641

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:40:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '0'	Bruce Bausk (b) (4)	23 Oct 2020 11:36:13

US3432641

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:40:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	23 Oct 2020 11:36:13

US3432641

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	Bruce Bausk (b) (4)	23 Oct 2020 11:36:13

US3432641

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:40:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '0'	Bruce Bausk (b) (4)	23 Oct 2020 11:36:13



US3432641

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User entered 'Jan 2000'	System	23 Oct 2020 11:36:13

US3432641

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:40:32

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User entered '2000'	System	23 Oct 2020 11:36:13

**US3432641**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:40:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User entered empty.	System	23 Oct 2020 11:36:13

**US3432641**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:40:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User entered empty.	System	23 Oct 2020 11:36:13

US3432641

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:40:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Mononeuropathies, PT: Carpal tunnel syndrome, LLT: Carpal tunnel syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	20 Jan 2021 16:16:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Jan 2021 16:16:06
Data point term sent to Coder	System	20 Jan 2021 16:15:00
User entered 'carpal tunnel'	(b) (4), (b) (6)	20 Jan 2021 16:14:55

**US3432641**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:40:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'un UNK 2018'	(b) (4), (b) (6)	20 Jan 2021 16:14:55

**US3432641**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:40:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '0'	(b) (4), (b) (6)	20 Jan 2021 16:14:55

US3432641

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:40:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 16:14:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Jan 2021 16:14:59
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Jan 2021 16:14:59
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 16:14:55
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 16:14:55



US3432641

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 16:14:55

**US3432641**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:40:32**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '0'	(b) (4), (b) (6)	20 Jan 2021 16:14:55

US3432641

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User entered 'Jan 2018'	System	20 Jan 2021 16:14:55

**US3432641**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:40:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User entered '2018'	System	20 Jan 2021 16:14:55

US3432641

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User entered empty.	System	20 Jan 2021 16:14:55

**US3432641**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:40:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User entered empty.	System	20 Jan 2021 16:14:55

US3432641

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	23 Oct 2020 11:30:17

US3432641

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '22 Oct 2020'	Bruce Bausk (b) (4)	23 Oct 2020 11:30:17



US3432641

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '11:32'	Bruce Bausk (b) (4)	23 Oct 2020 11:30:17

**US3432641**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:40:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User entered '22 Oct 2020 11:32'	System	23 Oct 2020 11:30:17

US3432641

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:32

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '154' cm	Bruce Bausk (b) (4)	23 Oct 2020 11:30:17
DataPoint set to visible.	(b) (4) System	22 Oct 2020 18:53:58

US3432641

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:32

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '92.3' kg	Bruce Bausk (b) (4)	23 Oct 2020 11:30:17
DataPoint set to visible.	(b) (4) System	22 Oct 2020 18:53:58

US3432641

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:32

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User entered '38.91887'	System	23 Oct 2020 11:30:17
DataPoint set to visible.	System	22 Oct 2020 18:53:58

US3432641

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:32

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User entered 'kg/m2'	System	23 Oct 2020 11:30:17
DataPoint set to visible.	System	22 Oct 2020 18:53:58

US3432641

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered missing code ND - Not Done.	Bruce Bausk (b) (4)	23 Oct 2020 11:30:17

US3432641

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	Bruce Bausk (b) (4)	23 Oct 2020 11:30:17



US3432641

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	Bruce Bausk (b) (4)	23 Oct 2020 11:30:17

US3432641

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered missing code ND - Not Done.	Bruce Bausk (b) (4)	23 Oct 2020 11:30:17

**US3432641**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:40:32**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User entered 'bpm'	System	23 Oct 2020 11:30:17

US3432641

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered missing code ND - Not Done.	Bruce Bausk (b) (4)	23 Oct 2020 11:30:17

US3432641

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User entered 'breaths/min'	System	23 Oct 2020 11:30:17

US3432641

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered missing code ND - Not Done.	Bruce Bausk (b) (4)	23 Oct 2020 11:30:17

US3432641

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User entered 'mmHg'	System	23 Oct 2020 11:30:17

US3432641

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered missing code ND - Not Done.	Bruce Bausk (b) (4)	23 Oct 2020 11:30:17



**US3432641**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:40:32**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User entered 'mmHg'	System	23 Oct 2020 11:30:17

US3432641

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:32

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29

US3432641

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:32

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29

US3432641

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:40:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	23 Oct 2020 11:30:56

US3432641

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:40:32

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '22 Oct 2020'	Bruce Bausk (b) (4)	23 Oct 2020 11:30:56

US3432641

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:40:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '22 Oct 2020'	Phoebe Cunningham (b) (4)	06 Nov 2020 15:25:53

US3432641

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:40:32

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	06 Nov 2020 15:25:53

US3432641

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:40:32

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	Phoebe Cunningham (b) (4)	06 Nov 2020 15:25:53



US3432641

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:40:32

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	Phoebe Cunningham (b) (4)	06 Nov 2020 15:25:53

US3432641

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:40:32

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	Phoebe Cunningham (b) (4)	06 Nov 2020 15:25:53

US3432641

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:40:32

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '0'	Phoebe Cunningham (b) (4)	06 Nov 2020 15:25:53

US3432641

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:40:32

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	Phoebe Cunningham (b) (4)	06 Nov 2020 15:25:53

US3432641

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:40:32

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '0'	Phoebe Cunningham (b) (4)	06 Nov 2020 15:25:53

US3432641

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:40:32

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	06 Nov 2020 15:26:15

US3432641

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:40:32

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '22 Oct 2020'	Phoebe Cunningham (b) (4)	06 Nov 2020 15:26:15

US3432641

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:40:32

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Urine (URINE)'	Phoebe Cunningham (b) (4)	06 Nov 2020 15:26:15



**US3432641**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:40:32**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Negative (NEGATIVE)'	Phoebe Cunningham (b) (4)	06 Nov 2020 15:26:15

US3432641

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:40:32

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'No (N)' reason for change: Data Entry Error	Monica Feeley (b) (4)	11 Nov 2020 16:41:45
User entered empty.	Phoebe Cunningham (b) (4)	06 Nov 2020 15:26:15

US3432641

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:40:32

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User closed query 'Per CDM: Response is required, kindly update as Yes/No' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 07:08:55
Query 'Per CDM: Response is required, kindly update as Yes/No' answered with 'updated' (Site from DM).	Monica Feeley (b) (4)	11 Nov 2020 16:42:05
User opened query 'Per CDM: Response is required, kindly update as Yes/No' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 14:27:53
User entered empty.	Phoebe Cunningham (b) (4)	06 Nov 2020 15:26:15

**US3432641**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:40:32**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	Phoebe Cunningham (b) (4)	06 Nov 2020 15:26:15

**US3432641**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:40:32**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User entered empty.	System	06 Nov 2020 15:26:15

US3432641

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:32

[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 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	23 Oct 2020 11:36:59

US3432641

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:32

**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 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'No (N)'	Bruce Bausk (b) (4)	23 Oct 2020 11:36:59

US3432641

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:32

**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 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'No (N)'	Bruce Bausk (b) (4)	23 Oct 2020 11:36:59



US3432641

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:32

**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 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'No (N)'	Bruce Bausk (b) (4)	23 Oct 2020 11:36:59

US3432641

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:32

[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 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'No (N)'	Bruce Bausk (b) (4)	23 Oct 2020 11:36:59

US3432641

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:32

[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 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'No (N)'	Bruce Bausk (b) (4)	23 Oct 2020 11:36:59

US3432641

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:32

**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 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'No (N)'	Bruce Bausk (b) (4)	23 Oct 2020 11:36:59

US3432641

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:32

**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 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'No (N)'	Bruce Bausk (b) (4)	23 Oct 2020 11:36:59

US3432641

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:32

**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 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'No (N)'	Bruce Bausk (b) (4)	23 Oct 2020 11:36:59

US3432641

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:32

**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 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'No (N)'	Bruce Bausk (b) (4)	23 Oct 2020 11:36:59

US3432641

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:32

**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 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'No (N)'	Bruce Bausk (b) (4)	23 Oct 2020 11:36:59



US3432641

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:32

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'No (N)'	Bruce Bausk (b) (4)	23 Oct 2020 11:36:59

US3432641

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:32

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	Bruce Bausk (b) (4)	23 Oct 2020 11:36:59

US3432641

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:32

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '0'	Bruce Bausk (b) (4)	23 Oct 2020 11:36:59

US3432641

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:32

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '0'	Bruce Bausk (b) (4)	23 Oct 2020 11:36:59

US3432641

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:32

**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 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'I'	Bruce Bausk (b) (4)	23 Oct 2020 11:36:59

US3432641

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:32

**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 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '0'	Bruce Bausk (b) (4)	23 Oct 2020 11:36:59

US3432641

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:32

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 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '0'	Bruce Bausk (b) (4)	23 Oct 2020 11:36:59

US3432641

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:32

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '0'	Bruce Bausk (b) (4)	23 Oct 2020 11:36:59



US3432641

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:32

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '0'	Bruce Bausk (b) (4)	23 Oct 2020 11:36:59

US3432641

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:40:32

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	Bruce Bausk (b) (4)	23 Oct 2020 11:36:59

US3432641

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:40:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	23 Oct 2020 11:37:09

US3432641

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '22 Oct 2020'	Bruce Bausk (b) (4)	23 Oct 2020 11:37:09

US3432641

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Clinic (Clinic)'	Bruce Bausk (b) (4)	23 Oct 2020 11:37:09

US3432641

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:40:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User entered 'VISIT1'	System	23 Oct 2020 11:37:09

US3432641

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '22 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Oct 2020 17:43:40

US3432641

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:40:32

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '117784'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Oct 2020 17:43:40



US3432641

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:40:32

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	22 Oct 2020 17:43:40

US3432641

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:40:32

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)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'No (N)'	Bruce Bausk (b) (4)	23 Oct 2020 11:38:20

US3432641

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:40:32

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)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'No (N)'	Bruce Bausk (b) (4)	23 Oct 2020 11:38:20

US3432641

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:40:32

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'No (N)'	Bruce Bausk (b) (4)	23 Oct 2020 11:38:20

US3432641

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:40:32

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'No (N)'	Bruce Bausk (b) (4)	23 Oct 2020 11:38:20

US3432641

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:40:32

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'No (N)'	Bruce Bausk (b) (4)	23 Oct 2020 11:38:20

US3432641

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:40:32

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'No (N)'	Bruce Bausk (b) (4)	23 Oct 2020 11:38:20
DataPoint set to visible.	(b) (4) System	22 Oct 2020 18:53:55

US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:40:32

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered missing code ND - Not Done.	Bruce Bausk (b) (4)	23 Oct 2020 11:45:40



US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:40:32

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered missing code ND - Not Done.	Bruce Bausk (b) (4)	23 Oct 2020 11:45:40

US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:40:32

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered missing code ND - Not Done.	Bruce Bausk (b) (4)	23 Oct 2020 11:45:40

US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:40:32

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered missing code ND - Not Done.	Bruce Bausk (b) (4)	23 Oct 2020 11:45:40

US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User accepted default value 'Pre-Dose (PREDOSE)'	Bruce Bausk (b) (4) (b) (4)	23 Oct 2020 11:45:40

US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	23 Oct 2020 11:45:40

US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '22 Oct 2020'	Bruce Bausk (b) (4)	23 Oct 2020 11:45:40

US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '13:32'	Bruce Bausk (b) (4)	23 Oct 2020 11:45:40

US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User entered '22 Oct 2020 13:32'	System	23 Oct 2020 11:45:40



US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '97.1' F	Bruce Bausk (b) (4)	23 Oct 2020 11:45:40

US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Oral (Oral)'	Bruce Bausk (b) (4)	23 Oct 2020 11:45:40

US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	Bruce Bausk (b) (4)	23 Oct 2020 11:45:40

US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '81'	Bruce Bausk (b) (4)	23 Oct 2020 11:45:40

US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User entered 'bpm'	System	23 Oct 2020 11:45:40

US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '14'	Bruce Bausk (b) (4)	23 Oct 2020 11:45:40

US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User entered 'breaths/min'	System	23 Oct 2020 11:45:40

US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '112'	Bruce Bausk (b) (4)	23 Oct 2020 11:45:40



US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User entered 'mmHg'	System	23 Oct 2020 11:45:40

US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 08:22:27
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Per clinician, pressure within normal range' (Site from System).	Megan Powell (b) (4)	10 Nov 2020 20:07:44
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		23 Oct 2020 11:45:40
User entered '58'	Bruce Bausk (b) (4)	23 Oct 2020 11:45:40

US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User entered 'mmHg'	System	23 Oct 2020 11:45:40

US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:40:32

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered missing code ND - Not Done.	Bruce Bausk (b) (4)	23 Oct 2020 11:45:40

US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:40:32

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered missing code ND - Not Done.	Bruce Bausk (b) (4)	23 Oct 2020 11:45:40

US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User accepted default value 'Post-Dose (POSTDOSE)'	Bruce Bausk (b) (4) (b) (4)	23 Oct 2020 11:45:40

US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	23 Oct 2020 11:45:40

US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '22 Oct 2020'	Bruce Bausk (b) (4)	23 Oct 2020 11:45:40



US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Oct 2020 11:46:26
User entered '15:13' reason for change: Data Entry Error	Bruce Bausk (b) (4)	23 Oct 2020 11:46:26
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Oct 2020 11:45:40
User entered '1:' (non-conformant).	Bruce Bausk (b) (4)	23 Oct 2020 11:45:40

US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User entered '22 Oct 2020 15:13'	System	23 Oct 2020 11:46:26
User entered '22 Oct 2020 1:' (non-conformant).	System	23 Oct 2020 11:45:40

US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User closed query 'Data is required. Please provide.' (Site from System).	System	23 Oct 2020 11:46:26
Query 'Data is required. Please provide.' answered by System data change (Site from System).		23 Oct 2020 11:46:26
User entered '97.5' F reason for change: Data Entry Error	Bruce Bausk (b) (4)	23 Oct 2020 11:46:26
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Oct 2020 11:45:40
User entered empty.	Bruce Bausk (b) (4)	23 Oct 2020 11:45:40

US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Other (Other)' reason for change: Data Entry Error	Bruce Bausk (b) (4)	23 Oct 2020 11:46:26
User entered empty.	Bruce Bausk (b) (4)	23 Oct 2020 11:45:40

US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'IR' reason for change: Data Entry Error	Bruce Bausk (b) (4)	23 Oct 2020 11:46:26
User entered empty.	Bruce Bausk (b) (4)	23 Oct 2020 11:45:40

US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User closed query 'Data is required. Please provide.' (Site from System).	System	23 Oct 2020 11:46:26
Query 'Data is required. Please provide.' answered by System data change (Site from System).		23 Oct 2020 11:46:26
User entered '89' reason for change: Data Entry Error	Bruce Bausk (b) (4)	23 Oct 2020 11:46:26
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Oct 2020 11:45:40
User entered empty.	Bruce Bausk (b) (4)	23 Oct 2020 11:45:40

US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User entered 'bpm'	System	23 Oct 2020 11:46:26
User entered empty.	System	23 Oct 2020 11:45:40

US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User closed query 'Data is required. Please provide.' (Site from System).	System	23 Oct 2020 11:46:26
Query 'Data is required. Please provide.' answered by System data change (Site from System).		23 Oct 2020 11:46:26
User entered '16' reason for change: Data Entry Error	Bruce Bausk (b) (4)	23 Oct 2020 11:46:26
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Oct 2020 11:45:40
User entered empty.	Bruce Bausk (b) (4)	23 Oct 2020 11:45:40



US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User entered 'breaths/min'	System	23 Oct 2020 11:46:26
User entered empty.	System	23 Oct 2020 11:45:40

US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User closed query 'Data is required. Please provide.' (Site from System).	System	23 Oct 2020 11:46:26
Query 'Data is required. Please provide.' answered by System data change (Site from System).		23 Oct 2020 11:46:26
User entered '124' reason for change: Data Entry Error	Bruce Bausk (b) (4)	23 Oct 2020 11:46:26
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Oct 2020 11:45:40
User entered empty.	Bruce Bausk (b) (4)	23 Oct 2020 11:45:40

US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User entered 'mmHg'	System	23 Oct 2020 11:46:26
User entered empty.	System	23 Oct 2020 11:45:40

US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User closed query 'Data is required. Please provide.' (Site from System).	System	23 Oct 2020 11:46:26
Query 'Data is required. Please provide.' answered by System data change (Site from System).		23 Oct 2020 11:46:26
User entered '69' reason for change: Data Entry Error	Bruce Bausk (b) (4)	23 Oct 2020 11:46:26
User opened query 'Data is required. Please provide.' (Site from System).	System	23 Oct 2020 11:45:40
User entered empty.	Bruce Bausk (b) (4)	23 Oct 2020 11:45:40

US3432641

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User entered 'mmHg'	System	23 Oct 2020 11:46:26
User entered empty.	System	23 Oct 2020 11:45:40

US3432641

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:40:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'No (N)'	Bruce Bausk (b) (4)	23 Oct 2020 11:47:09

US3432641

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:40:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	Bruce Bausk (b) (4)	23 Oct 2020 11:47:09

US3432641

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:40:32

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'No (N)'	Phoebe Cunningham (b) (4)	06 Nov 2020 15:27:18



US3432641

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:40:32

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	Phoebe Cunningham (b) (4)	06 Nov 2020 15:27:18

US3432641

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:40:32

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	Phoebe Cunningham (b) (4)	06 Nov 2020 15:27:18

US3432641

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:40:32

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	Phoebe Cunningham (b) (4)	06 Nov 2020 15:27:18

US3432641

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:40:32

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User closed query 'Per CDM: Response is required, kindly update as Yes/No' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 07:27:26
Query 'Per CDM: Response is required, kindly update as Yes/No' answered with 'updated' (Site from DM).	Monica Feeley (b) (4)	11 Nov 2020 16:41:32
User entered 'No (N)' reason for change: Data Entry Error	Monica Feeley (b) (4)	11 Nov 2020 16:41:27
User opened query 'Per CDM: Response is required, kindly update as Yes/No' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 14:35:59
User entered empty.	Phoebe Cunningham (b) (4)	06 Nov 2020 15:27:18

US3432641

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:40:32

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	Phoebe Cunningham (b) (4)	06 Nov 2020 15:27:18

US3432641

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:40:32

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	Phoebe Cunningham (b) (4)	06 Nov 2020 15:27:18

US3432641

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:40:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User entered empty.	System	06 Nov 2020 15:27:18

US3432641

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:40:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	22 Oct 2020 18:54:23



US3432641

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:40:32

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	Bruce Bausk (b) (4)	22 Oct 2020 18:54:23

US3432641

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:40:32

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)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	Bruce Bausk (b) (4)	22 Oct 2020 18:54:23

US3432641

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:40:32

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User entered 'MRNA-1273 OR PLACEBO'	System	22 Oct 2020 18:54:23

US3432641

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:40:32

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '22 Oct 2020'	Bruce Bausk (b) (4)	22 Oct 2020 18:54:23

US3432641

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:40:32

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '14:43'	Bruce Bausk (b) (4)	22 Oct 2020 18:54:23

US3432641

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:40:32

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User entered '22 Oct 2020 14:43'	System	22 Oct 2020 18:54:23

US3432641

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:40:32

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Left Arm (LEFT ARM)'	Bruce Bausk (b) (4)	22 Oct 2020 18:54:23

US3432641

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:40:32

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User entered 'ONCE'	System	22 Oct 2020 18:54:23



US3432641

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:40:32

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User entered 'INTRAMUSCULAR'	System	22 Oct 2020 18:54:23

US3432641

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	23 Oct 2020 11:47:54

US3432641

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:32

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '22 Oct 2020'	Bruce Bausk (b) (4)	23 Oct 2020 11:47:54

US3432641

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '13:39'	Bruce Bausk (b) (4)	23 Oct 2020 11:47:54

US3432641

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User entered '22 Oct 2020 13:39'	System	23 Oct 2020 11:47:54

US3432641

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:40:32

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '22 Oct 2020'	Bruce Bausk (b) (4)	23 Oct 2020 11:48:08

US3432641

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:40:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Bruce Bausk (b) (4) (b) (4)	23 Oct 2020 11:48:08

US3432641

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:40:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	23 Oct 2020 11:48:08



US3432641

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:40:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '13:45'	Bruce Bausk (b) (4)	23 Oct 2020 11:48:08

US3432641

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:40:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User entered '22 Oct 2020 13:45'	System	23 Oct 2020 11:48:08

US3432641

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:40:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Bruce Bausk (b) (4) (b) (4)	23 Oct 2020 11:48:08

US3432641

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:40:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'No (N)'	Bruce Bausk (b) (4)	23 Oct 2020 11:48:08

US3432641

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:40:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	Bruce Bausk (b) (4)	23 Oct 2020 11:48:08

US3432641

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:40:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User entered empty.	System	23 Oct 2020 11:48:08

US3432641

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:40:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	23 Oct 2020 11:48:46

**US3432641**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:40:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User entered 'l'	System	23 Oct 2020 11:48:46



US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	22 Oct 2020 18:54:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-22T15:16:25', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '78caf877-126b-4f2d-b840-f1d412a6a84f' User entered 'Yes (Y)'	System	22 Oct 2020 19:16:46
	System	22 Oct 2020 19:16:46

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-22T15:16:34', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '78caf877-126b-4f2d-b840-f1d412a6a84f' User entered '97.5'	System	22 Oct 2020 19:16:46
	System	22 Oct 2020 19:16:46

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-22T15:16:37', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '78caf877-126b-4f2d-b840-f1d412a6a84f' User entered 'No (N)'	System	22 Oct 2020 19:16:46
	System	22 Oct 2020 19:16:46

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-22T15:16:43', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '78caf877-126b-4f2d-b840-f1d412a6a84f' User entered '22 Oct 2020 15:16'	System	22 Oct 2020 19:16:46
	System	22 Oct 2020 19:16:46

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '22 Oct 2020 15:03'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '22 Oct 2020 17:33'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	22 Oct 2020 18:54:23
User entered 'Day 1, after vaccination (at home)'	System	22 Oct 2020 18:54:23



US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-22T19:08:17', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'cc88ac90-4490-4bd1-a483-7d3d7b99cfb1' User entered 'Yes (Y)'	System	22 Oct 2020 23:08:36
	System	22 Oct 2020 23:08:36

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-22T19:08:23', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'cc88ac90-4490-4bd1-a483-7d3d7b99cfb1' User entered '97.6'	System	22 Oct 2020 23:08:36
	System	22 Oct 2020 23:08:36

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-22T19:08:29', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'cc88ac90-4490-4bd1-a483-7d3d7b99cfb1' User entered 'No (N)'	System	22 Oct 2020 23:08:36
	System	22 Oct 2020 23:08:36

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-22T19:08:32', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'cc88ac90-4490-4bd1-a483-7d3d7b99cfb1' User entered '22 Oct 2020 19:08'	System	22 Oct 2020 23:08:36
	System	22 Oct 2020 23:08:36

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '22 Oct 2020 18:28'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '23 Oct 2020 11:59'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	22 Oct 2020 18:54:23
User entered 'Day 2'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:40:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-23T21:58:42', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'dcb09398-046b-4199-b130-12b63590fb09' User entered 'Yes (Y)'	System	24 Oct 2020 01:59:00
	System	24 Oct 2020 01:59:00



US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:40:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-23T21:58:50', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'dcb09398-046b-4199-b130-12b63590fb09' User entered '97.9'	System	24 Oct 2020 01:59:00
	System	24 Oct 2020 01:59:00

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-23T21:58:55', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'dcb09398-046b-4199-b130-12b63590fb09'	System	24 Oct 2020 01:59:00
User entered 'No (N)'	System	24 Oct 2020 01:59:00

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:40:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-23T21:58:59', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'dcb09398-046b-4199-b130-12b63590fb09' User entered '23 Oct 2020 21:58'	System	24 Oct 2020 01:59:00
	System	24 Oct 2020 01:59:00

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	22 Oct 2020 18:54:23
User entered 'Day 3'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:40:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-24T16:29:59', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '4fae0f55-d501-40c8-9106-6e58e33acd20' User entered 'Yes (Y)'	System	24 Oct 2020 20:30:11
	System	24 Oct 2020 20:30:11

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:40:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-24T16:30:03', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '4fae0f55-d501-40c8-9106-6e58e33acd20' User entered '98.2'	System	24 Oct 2020 20:30:11
	System	24 Oct 2020 20:30:11



US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-24T16:30:07', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '4fae0f55-d501-40c8-9106-6e58e33acd20'	System	24 Oct 2020 20:30:11
User entered 'No (N)'	System	24 Oct 2020 20:30:11

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:40:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-24T16:30:09', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '4fae0f55-d501-40c8-9106-6e58e33acd20' User entered '24 Oct 2020 16:30'	System	24 Oct 2020 20:30:11
	System	24 Oct 2020 20:30:11

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	22 Oct 2020 18:54:23
User entered 'Day 4'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:40:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-25T14:53:05', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '28d4bef1-7a0e-4640-a651-357870f82406'	System	25 Oct 2020 18:54:44
User entered 'Yes (Y)'	System	25 Oct 2020 18:54:44

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:40:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-25T14:54:35', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '28d4bef1-7a0e-4640-a651-357870f82406' User entered '97.5'	System	25 Oct 2020 18:54:44
	System	25 Oct 2020 18:54:44

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-25T14:54:39', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '28d4bef1-7a0e-4640-a651-357870f82406'	System	25 Oct 2020 18:54:44
User entered 'No (N)'	System	25 Oct 2020 18:54:44



US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:40:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-25T14:54:42', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '28d4bef1-7a0e-4640-a651-357870f82406'	System	25 Oct 2020 18:54:44
User entered '25 Oct 2020 14:54'	System	25 Oct 2020 18:54:44

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '25 Oct 2020 12:00'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '26 Oct 2020 11:59'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	22 Oct 2020 18:54:23
User entered 'Day 5'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:40:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-26T18:09:59', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'cb05699d-3ca7-4e81-9977-1f36cc94530a' User entered 'Yes (Y)'	System	26 Oct 2020 22:10:15
	System	26 Oct 2020 22:10:15

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:40:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-26T18:10:04', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'cb05699d-3ca7-4e81-9977-1f36cc94530a' User entered '97.5'	System	26 Oct 2020 22:10:15
	System	26 Oct 2020 22:10:15

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-26T18:10:08', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'cb05699d-3ca7-4e81-9977-1f36cc94530a' User entered 'No (N)'	System	26 Oct 2020 22:10:15
	System	26 Oct 2020 22:10:15

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:40:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-26T18:10:12', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'cb05699d-3ca7-4e81-9977-1f36cc94530a' User entered '26 Oct 2020 18:10'	System	26 Oct 2020 22:10:15
	System	26 Oct 2020 22:10:15



US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '26 Oct 2020 12:00'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '27 Oct 2020 11:59'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	22 Oct 2020 18:54:23
User entered 'Day 6'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:40:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-28T08:06:57', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'e8e8e214-f8bb-40e3-9fea-7dc9d457a662'	System	28 Oct 2020 12:07:09
User entered 'Yes (Y)'	System	28 Oct 2020 12:07:09

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:40:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-28T08:07:01', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'e8e8e214-f8bb-40e3-9fea-7dc9d457a662'	System	28 Oct 2020 12:07:09
User entered '97.3'	System	28 Oct 2020 12:07:09

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-28T08:07:04', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'e8e8e214-f8bb-40e3-9fea-7dc9d457a662'	System	28 Oct 2020 12:07:09
User entered 'No (N)'	System	28 Oct 2020 12:07:09

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:40:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-28T08:07:06', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'e8e8e214-f8bb-40e3-9fea-7dc9d457a662'	System	28 Oct 2020 12:07:09
User entered '28 Oct 2020 08:07'	System	28 Oct 2020 12:07:09

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '27 Oct 2020 12:00'	System	22 Oct 2020 18:54:23



US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '28 Oct 2020 11:59'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	22 Oct 2020 18:54:23
User entered 'Day 7'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:40:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-29T08:33:54', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '9d9395e6-445b-4b79-a6dc-38307e28a413' User entered 'Yes (Y)'	System	29 Oct 2020 12:34:12
	System	29 Oct 2020 12:34:12

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:40:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-29T08:33:59', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '9d9395e6-445b-4b79-a6dc-38307e28a413' User entered '97.2'	System	29 Oct 2020 12:34:12
	System	29 Oct 2020 12:34:12

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-29T08:34:07', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '9d9395e6-445b-4b79-a6dc-38307e28a413'	System	29 Oct 2020 12:34:12
User entered 'No (N)'	System	29 Oct 2020 12:34:12

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:40:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-29T08:34:10', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '9d9395e6-445b-4b79-a6dc-38307e28a413' User entered '29 Oct 2020 08:34'	System	29 Oct 2020 12:34:12
	System	29 Oct 2020 12:34:12

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '28 Oct 2020 12:00'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '29 Oct 2020 11:59'	System	22 Oct 2020 18:54:23



US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	22 Oct 2020 18:54:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-22T15:17:17', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'b1130cff-0fc7-43fd-a8be-854d0ddd169b'	System	22 Oct 2020 19:17:50
User entered 'None (1)'	System	22 Oct 2020 19:17:50

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-22T15:17:28', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'b1130cff-0fc7-43fd-a8be-854d0ddd169b' User entered 'No (N)'	System	22 Oct 2020 19:17:50
	System	22 Oct 2020 19:17:50

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-22T15:17:37', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'b1130cff-0fc7-43fd-a8be-854d0ddd169b'	System	22 Oct 2020 19:17:50
User entered 'No (N)'	System	22 Oct 2020 19:17:50

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-22T15:17:43', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'b1130cff-0fc7-43fd-a8be-854d0ddd169b'	System	22 Oct 2020 19:17:50
User entered 'None (1)'	System	22 Oct 2020 19:17:50

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-22T15:17:47', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'b1130cff-0fc7-43fd-a8be-854d0ddd169b' User entered '22 Oct 2020 15:17'	System	22 Oct 2020 19:17:50
	System	22 Oct 2020 19:17:50

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '22 Oct 2020 15:03'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '22 Oct 2020 17:33'	System	22 Oct 2020 18:54:23



US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	22 Oct 2020 18:54:23
User entered 'Day 1, after vaccination (at home)'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-22T19:08:40', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'aeb5723d-18c3-4bb5-881a-b3f10e292bde'	System	22 Oct 2020 23:09:30
User entered 'Does not interfere with activity (2)'	System	22 Oct 2020 23:09:30

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-22T19:08:47', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'aeb5723d-18c3-4bb5-881a-b3f10e292bde' User entered 'No (N)'	System	22 Oct 2020 23:09:30
	System	22 Oct 2020 23:09:30

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-22T19:09:15', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'aeb5723d-18c3-4bb5-881a-b3f10e292bde' User entered 'No (N)'	System	22 Oct 2020 23:09:30
	System	22 Oct 2020 23:09:30

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-22T19:09:21', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'aeb5723d-18c3-4bb5-881a-b3f10e292bde' User entered 'None (1)'	System	22 Oct 2020 23:09:30
	System	22 Oct 2020 23:09:30

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-22T19:09:24', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'aeb5723d-18c3-4bb5-881a-b3f10e292bde' User entered '22 Oct 2020 19:09'	System	22 Oct 2020 23:09:30
	System	22 Oct 2020 23:09:30

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '22 Oct 2020 18:28'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '23 Oct 2020 11:59'	System	22 Oct 2020 18:54:23



US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	22 Oct 2020 18:54:23
User entered 'Day 2'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-23T21:59:12', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '7026e0a6-5a7b-4c35-bfb1-98dccf773f57'	System	24 Oct 2020 01:59:32
User entered 'Does not interfere with activity (2)'	System	24 Oct 2020 01:59:32

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:40:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-23T21:59:15', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '7026e0a6-5a7b-4c35-bfb1-98dccf773f57'	System	24 Oct 2020 01:59:32
User entered 'No (N)'	System	24 Oct 2020 01:59:32

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-23T21:59:22', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '7026e0a6-5a7b-4c35-bfb1-98dccf773f57'	System	24 Oct 2020 01:59:32
User entered 'No (N)'	System	24 Oct 2020 01:59:32

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-23T21:59:26', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '7026e0a6-5a7b-4c35-bfb1-98dccf773f57'	System	24 Oct 2020 01:59:32
User entered 'None (1)'	System	24 Oct 2020 01:59:32

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:40:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-23T21:59:30', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '7026e0a6-5a7b-4c35-bfb1-98dccf773f57' User entered '23 Oct 2020 21:59'	System	24 Oct 2020 01:59:32
	System	24 Oct 2020 01:59:32

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 18:54:23



US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	22 Oct 2020 18:54:23
User entered 'Day 3'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-24T16:30:14', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '0f2d7e59-b72c-479a-814b-38e3a05b0c56'	System	24 Oct 2020 20:30:27
User entered 'Does not interfere with activity (2)'	System	24 Oct 2020 20:30:27

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:40:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-24T16:30:16', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '0f2d7e59-b72c-479a-814b-38e3a05b0c56' User entered 'No (N)'	System	24 Oct 2020 20:30:27
	System	24 Oct 2020 20:30:27

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-24T16:30:18', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '0f2d7e59-b72c-479a-814b-38e3a05b0c56' User entered 'No (N)'	System	24 Oct 2020 20:30:27
	System	24 Oct 2020 20:30:27

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-24T16:30:19', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '0f2d7e59-b72c-479a-814b-38e3a05b0c56'	System	24 Oct 2020 20:30:27
User entered 'None (1)'	System	24 Oct 2020 20:30:27

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:40:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-24T16:30:23', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '0f2d7e59-b72c-479a-814b-38e3a05b0c56' User entered '24 Oct 2020 16:30'	System	24 Oct 2020 20:30:27
	System	24 Oct 2020 20:30:27

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 18:54:23



US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	22 Oct 2020 18:54:23
User entered 'Day 4'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-25T14:54:45', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '70be3c19-7bb7-4adb-b542-8b83d5cc6567'	System	25 Oct 2020 18:54:58
User entered 'None (1)'	System	25 Oct 2020 18:54:58

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:40:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-25T14:54:48', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '70be3c19-7bb7-4adb-b542-8b83d5cc6567' User entered 'No (N)'	System	25 Oct 2020 18:54:58
	System	25 Oct 2020 18:54:58

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-25T14:54:50', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '70be3c19-7bb7-4adb-b542-8b83d5cc6567' User entered 'No (N)'	System	25 Oct 2020 18:54:58
	System	25 Oct 2020 18:54:58

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-25T14:54:52', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '70be3c19-7bb7-4adb-b542-8b83d5cc6567' User entered 'None (1)'	System	25 Oct 2020 18:54:58
	System	25 Oct 2020 18:54:58

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:40:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-25T14:54:55', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '70be3c19-7bb7-4adb-b542-8b83d5cc6567' User entered '25 Oct 2020 14:54'	System	25 Oct 2020 18:54:58
	System	25 Oct 2020 18:54:58

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '25 Oct 2020 12:00'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '26 Oct 2020 11:59'	System	22 Oct 2020 18:54:23



US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	22 Oct 2020 18:54:23
User entered 'Day 5'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-26T18:10:19', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '3e906964-1d9a-4866-9bc4-5dd499d7ce10'	System	26 Oct 2020 22:10:29
User entered 'None (1)'	System	26 Oct 2020 22:10:29

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:40:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-26T18:10:21', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '3e906964-1d9a-4866-9bc4-5dd499d7ce10' User entered 'No (N)'	System	26 Oct 2020 22:10:29
	System	26 Oct 2020 22:10:29

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-26T18:10:22', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '3e906964-1d9a-4866-9bc4-5dd499d7ce10' User entered 'No (N)'	System	26 Oct 2020 22:10:29
	System	26 Oct 2020 22:10:29

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-26T18:10:23', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '3e906964-1d9a-4866-9bc4-5dd499d7ce10' User entered 'None (1)'	System	26 Oct 2020 22:10:29
	System	26 Oct 2020 22:10:29

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:40:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-26T18:10:26', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '3e906964-1d9a-4866-9bc4-5dd499d7ce10' User entered '26 Oct 2020 18:10'	System	26 Oct 2020 22:10:29
	System	26 Oct 2020 22:10:29

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '26 Oct 2020 12:00'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '27 Oct 2020 11:59'	System	22 Oct 2020 18:54:23



US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	22 Oct 2020 18:54:23
User entered 'Day 6'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-28T08:07:10', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '641cbf5b-dc7f-4cce-b543-dba65bd49ca1'	System	28 Oct 2020 12:07:19
User entered 'None (1)'	System	28 Oct 2020 12:07:19

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:40:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-28T08:07:12', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '641cbf5b-dc7f-4cce-b543-dba65bd49ca1' User entered 'No (N)'	System	28 Oct 2020 12:07:19
	System	28 Oct 2020 12:07:19

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-28T08:07:13', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '641cbf5b-dc7f-4cce-b543-dba65bd49ca1' User entered 'No (N)'	System	28 Oct 2020 12:07:19
	System	28 Oct 2020 12:07:19

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-28T08:07:14', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '641cbf5b-dc7f-4cce-b543-dba65bd49ca1'	System	28 Oct 2020 12:07:19
User entered 'None (1)'	System	28 Oct 2020 12:07:19

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:40:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-28T08:07:17', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '641cbf5b-dc7f-4cce-b543-dba65bd49ca1' User entered '28 Oct 2020 08:07'	System	28 Oct 2020 12:07:19
	System	28 Oct 2020 12:07:19

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '27 Oct 2020 12:00'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '28 Oct 2020 11:59'	System	22 Oct 2020 18:54:23



US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	22 Oct 2020 18:54:23
User entered 'Day 7'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-29T08:34:14', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'b202b7b8-ffe9-4dc9-8601-15e56cce1b10'	System	29 Oct 2020 12:34:27
User entered 'None (1)'	System	29 Oct 2020 12:34:27

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:40:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-29T08:34:16', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'b202b7b8-ffe9-4dc9-8601-15e56cce1b10' User entered 'No (N)'	System	29 Oct 2020 12:34:27
	System	29 Oct 2020 12:34:27

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-29T08:34:18', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'b202b7b8-ffe9-4dc9-8601-15e56cce1b10' User entered 'No (N)'	System	29 Oct 2020 12:34:27
	System	29 Oct 2020 12:34:27

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-29T08:34:19', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'b202b7b8-ffe9-4dc9-8601-15e56cce1b10'	System	29 Oct 2020 12:34:27
User entered 'None (1)'	System	29 Oct 2020 12:34:27

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:40:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-29T08:34:23', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'b202b7b8-ffe9-4dc9-8601-15e56cce1b10' User entered '29 Oct 2020 08:34'	System	29 Oct 2020 12:34:27
	System	29 Oct 2020 12:34:27

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '28 Oct 2020 12:00'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '29 Oct 2020 11:59'	System	22 Oct 2020 18:54:23



US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	22 Oct 2020 18:54:23
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-22T15:18:20', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'd2c3efd9-c932-48b1-9de5-47f30988f338'	System	22 Oct 2020 19:19:13
User entered 'None (0)'	System	22 Oct 2020 19:19:13

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-22T15:18:31', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'd2c3efd9-c932-48b1-9de5-47f30988f338' User entered 'None (0)'	System	22 Oct 2020 19:19:13
	System	22 Oct 2020 19:19:13

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-22T15:18:34', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'd2c3efd9-c932-48b1-9de5-47f30988f338' User entered 'None (0)'	System	22 Oct 2020 19:19:13
	System	22 Oct 2020 19:19:13

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-22T15:18:37', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'd2c3efd9-c932-48b1-9de5-47f30988f338' User entered 'None (0)'	System	22 Oct 2020 19:19:13
	System	22 Oct 2020 19:19:13

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-22T15:18:41', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'd2c3efd9-c932-48b1-9de5-47f30988f338' User entered 'None (0)'	System	22 Oct 2020 19:19:13
	System	22 Oct 2020 19:19:13

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-22T15:18:43', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'd2c3efd9-c932-48b1-9de5-47f30988f338' User entered 'None (0)'	System	22 Oct 2020 19:19:13
	System	22 Oct 2020 19:19:13

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-22T15:19:07', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'd2c3efd9-c932-48b1-9de5-47f30988f338'	System	22 Oct 2020 19:19:13
User entered 'No (N)'	System	22 Oct 2020 19:19:13



US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-22T15:19:10', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'd2c3efd9-c932-48b1-9de5-47f30988f338' User entered '22 Oct 2020 15:19'	System	22 Oct 2020 19:19:13
	System	22 Oct 2020 19:19:13

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '22 Oct 2020 15:03'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '22 Oct 2020 17:33'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	22 Oct 2020 18:54:23
User entered 'Day 1, after vaccination (at home)'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-22T19:09:31', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '8ad1d120-ad0b-4abb-a0fe-807042e1c636' User entered 'None (0)'	System	22 Oct 2020 23:09:50
	System	22 Oct 2020 23:09:50

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-22T19:09:34', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '8ad1d120-ad0b-4abb-a0fe-807042e1c636' User entered 'None (0)'	System	22 Oct 2020 23:09:50
	System	22 Oct 2020 23:09:50

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-22T19:09:37', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '8ad1d120-ad0b-4abb-a0fe-807042e1c636' User entered 'None (0)'	System	22 Oct 2020 23:09:50
	System	22 Oct 2020 23:09:50

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-22T19:09:38', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '8ad1d120-ad0b-4abb-a0fe-807042e1c636' User entered 'None (0)'	System	22 Oct 2020 23:09:50
	System	22 Oct 2020 23:09:50



US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-22T19:09:40', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '8ad1d120-ad0b-4abb-a0fe-807042e1c636' User entered 'None (0)'	System	22 Oct 2020 23:09:50
	System	22 Oct 2020 23:09:50

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-22T19:09:42', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '8ad1d120-ad0b-4abb-a0fe-807042e1c636' User entered 'None (0)'	System	22 Oct 2020 23:09:50
	System	22 Oct 2020 23:09:50

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-22T19:09:44', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '8ad1d120-ad0b-4abb-a0fe-807042e1c636'	System	22 Oct 2020 23:09:50
User entered 'No (N)'	System	22 Oct 2020 23:09:50

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-22T19:09:47', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '8ad1d120-ad0b-4abb-a0fe-807042e1c636' User entered '22 Oct 2020 19:09'	System	22 Oct 2020 23:09:50
	System	22 Oct 2020 23:09:50

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '22 Oct 2020 18:28'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '23 Oct 2020 11:59'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	22 Oct 2020 18:54:23
User entered 'Day 2'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:40:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-23T21:59:35', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '4877f9fd-8c73-46eb-a9f9-2ab3279c221d' User entered 'None (0)'	System	24 Oct 2020 02:00:07
	System	24 Oct 2020 02:00:07



US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:40:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-23T21:59:36', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '4877f9fd-8c73-46eb-a9f9-2ab3279c221d' User entered 'None (0)'	System	24 Oct 2020 02:00:07
	System	24 Oct 2020 02:00:07

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:40:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-23T21:59:40', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '4877f9fd-8c73-46eb-a9f9-2ab3279c221d' User entered 'None (0)'	System	24 Oct 2020 02:00:07
	System	24 Oct 2020 02:00:07

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:40:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-23T21:59:44', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '4877f9fd-8c73-46eb-a9f9-2ab3279c221d' User entered 'None (0)'	System	24 Oct 2020 02:00:07
	System	24 Oct 2020 02:00:07

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:40:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-23T21:59:46', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '4877f9fd-8c73-46eb-a9f9-2ab3279c221d' User entered 'None (0)'	System	24 Oct 2020 02:00:07
	System	24 Oct 2020 02:00:07

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:40:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-23T21:59:54', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '4877f9fd-8c73-46eb-a9f9-2ab3279c221d' User entered 'None (0)'	System	24 Oct 2020 02:00:07
	System	24 Oct 2020 02:00:07

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-23T21:59:57', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '4877f9fd-8c73-46eb-a9f9-2ab3279c221d' User entered 'No (N)'	System	24 Oct 2020 02:00:07
	System	24 Oct 2020 02:00:07

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:40:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-23T22:00:01', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '4877f9fd-8c73-46eb-a9f9-2ab3279c221d' User entered '23 Oct 2020 22:00'	System	24 Oct 2020 02:00:07
	System	24 Oct 2020 02:00:07

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 18:54:23



US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	22 Oct 2020 18:54:23
User entered 'Day 3'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:40:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-24T16:30:40', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'bde45bd1-322a-44e0-b469-e7b93b3d5349' User entered 'None (0)'	System	24 Oct 2020 20:31:00
	System	24 Oct 2020 20:31:00

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:40:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-24T16:30:42', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'bde45bd1-322a-44e0-b469-e7b93b3d5349' User entered 'None (0)'	System	24 Oct 2020 20:31:00
	System	24 Oct 2020 20:31:00

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:40:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-24T16:30:43', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'bde45bd1-322a-44e0-b469-e7b93b3d5349' User entered 'None (0)'	System	24 Oct 2020 20:31:00
	System	24 Oct 2020 20:31:00

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:40:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-24T16:30:44', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'bde45bd1-322a-44e0-b469-e7b93b3d5349' User entered 'None (0)'	System	24 Oct 2020 20:31:00
	System	24 Oct 2020 20:31:00

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:40:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-24T16:30:46', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'bde45bd1-322a-44e0-b469-e7b93b3d5349' User entered 'None (0)'	System	24 Oct 2020 20:31:00
	System	24 Oct 2020 20:31:00

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:40:32

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-24T16:30:47', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'bde45bd1-322a-44e0-b469-e7b93b3d5349' User entered 'None (0)'	System	24 Oct 2020 20:31:00
	System	24 Oct 2020 20:31:00



US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-24T16:30:49', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'bde45bd1-322a-44e0-b469-e7b93b3d5349' User entered 'No (N)'	System	24 Oct 2020 20:31:00
	System	24 Oct 2020 20:31:00

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:40:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-24T16:30:54', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'bde45bd1-322a-44e0-b469-e7b93b3d5349' User entered '24 Oct 2020 16:30'	System	24 Oct 2020 20:31:00
	System	24 Oct 2020 20:31:00

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '24 Oct 2020 12:00'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '25 Oct 2020 11:59'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	22 Oct 2020 18:54:23
User entered 'Day 4'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:40:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-25T14:54:59', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'a03e2f97-d1b0-4b7f-bd4d-9f402c83bd97'	System	25 Oct 2020 18:55:20
User entered 'No interference with activity (1)'	System	25 Oct 2020 18:55:20

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:40:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-25T14:55:02', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'a03e2f97-d1b0-4b7f-bd4d-9f402c83bd97'	System	25 Oct 2020 18:55:20
User entered 'Some interference with activity (2)'	System	25 Oct 2020 18:55:20

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:40:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-25T14:55:06', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'a03e2f97-d1b0-4b7f-bd4d-9f402c83bd97' User entered 'None (0)'	System	25 Oct 2020 18:55:20
	System	25 Oct 2020 18:55:20



US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:40:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-25T14:55:08', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'a03e2f97-d1b0-4b7f-bd4d-9f402c83bd97' User entered 'None (0)'	System	25 Oct 2020 18:55:20
	System	25 Oct 2020 18:55:20

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:40:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-25T14:55:10', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'a03e2f97-d1b0-4b7f-bd4d-9f402c83bd97' User entered 'None (0)'	System	25 Oct 2020 18:55:20
	System	25 Oct 2020 18:55:20

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:40:32

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-25T14:55:12', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'a03e2f97-d1b0-4b7f-bd4d-9f402c83bd97' User entered 'None (0)'	System	25 Oct 2020 18:55:20
	System	25 Oct 2020 18:55:20

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-25T14:55:14', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'a03e2f97-d1b0-4b7f-bd4d-9f402c83bd97'	System	25 Oct 2020 18:55:20
User entered 'No (N)'	System	25 Oct 2020 18:55:20

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:40:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-25T14:55:17', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'a03e2f97-d1b0-4b7f-bd4d-9f402c83bd97' User entered '25 Oct 2020 14:55'	System	25 Oct 2020 18:55:20
	System	25 Oct 2020 18:55:20

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '25 Oct 2020 12:00'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '26 Oct 2020 11:59'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	22 Oct 2020 18:54:23
User entered 'Day 5'	System	22 Oct 2020 18:54:23



US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:40:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-26T18:10:35', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '6b5a1f6d-99a6-4017-86b4-0a8e4555efba'	System	26 Oct 2020 22:10:59
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	26 Oct 2020 22:10:59

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:40:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-26T18:10:41', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '6b5a1f6d-99a6-4017-86b4-0a8e4555efba' User entered 'No interference with activity (1)'	System	26 Oct 2020 22:10:59
	System	26 Oct 2020 22:10:59

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:40:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-26T18:10:44', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '6b5a1f6d-99a6-4017-86b4-0a8e4555efba' User entered 'None (0)'	System	26 Oct 2020 22:10:59
	System	26 Oct 2020 22:10:59

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:40:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-26T18:10:45', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '6b5a1f6d-99a6-4017-86b4-0a8e4555efba' User entered 'None (0)'	System	26 Oct 2020 22:10:59
	System	26 Oct 2020 22:10:59

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:40:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-26T18:10:49', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '6b5a1f6d-99a6-4017-86b4-0a8e4555efba' User entered 'None (0)'	System	26 Oct 2020 22:10:59
	System	26 Oct 2020 22:10:59

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:40:32

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-26T18:10:50', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '6b5a1f6d-99a6-4017-86b4-0a8e4555efba' User entered 'None (0)'	System	26 Oct 2020 22:10:59
	System	26 Oct 2020 22:10:59

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-26T18:10:52', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '6b5a1f6d-99a6-4017-86b4-0a8e4555efba' User entered 'No (N)'	System	26 Oct 2020 22:10:59
	System	26 Oct 2020 22:10:59

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:40:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-26T18:10:57', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '6b5a1f6d-99a6-4017-86b4-0a8e4555efba' User entered '26 Oct 2020 18:10'	System	26 Oct 2020 22:10:59
	System	26 Oct 2020 22:10:59



US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '26 Oct 2020 12:00'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '27 Oct 2020 11:59'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	22 Oct 2020 18:54:23
User entered 'Day 6'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:40:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-28T08:07:19', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'a7c6a8ea-b282-4ed3-80a5-2313f7f8c8cf' User entered 'None (0)'	System	28 Oct 2020 12:07:32
	System	28 Oct 2020 12:07:32

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:40:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-28T08:07:21', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'a7c6a8ea-b282-4ed3-80a5-2313f7f8c8cf' User entered 'None (0)'	System	28 Oct 2020 12:07:32
	System	28 Oct 2020 12:07:32

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:40:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-28T08:07:22', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'a7c6a8ea-b282-4ed3-80a5-2313f7f8c8cf' User entered 'None (0)'	System	28 Oct 2020 12:07:32
	System	28 Oct 2020 12:07:32

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:40:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-28T08:07:23', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'a7c6a8ea-b282-4ed3-80a5-2313f7f8c8cf' User entered 'None (0)'	System	28 Oct 2020 12:07:32
	System	28 Oct 2020 12:07:32

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:40:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-28T08:07:25', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'a7c6a8ea-b282-4ed3-80a5-2313f7f8c8cf' User entered 'None (0)'	System	28 Oct 2020 12:07:32
	System	28 Oct 2020 12:07:32



US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:40:32

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-28T08:07:26', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'a7c6a8ea-b282-4ed3-80a5-2313f7f8c8cf' User entered 'None (0)'	System	28 Oct 2020 12:07:32
	System	28 Oct 2020 12:07:32

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-28T08:07:27', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'a7c6a8ea-b282-4ed3-80a5-2313f7f8c8cf' User entered 'No (N)'	System	28 Oct 2020 12:07:32
	System	28 Oct 2020 12:07:32

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:40:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-28T08:07:31', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'a7c6a8ea-b282-4ed3-80a5-2313f7f8c8cf' User entered '28 Oct 2020 08:07'	System	28 Oct 2020 12:07:32
	System	28 Oct 2020 12:07:32

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '27 Oct 2020 12:00'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '28 Oct 2020 11:59'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	22 Oct 2020 18:54:23
User entered 'Day 7'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:40:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-29T08:34:26', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '85cc7805-4109-4e27-8886-a5b913c80ad9' User entered 'None (0)'	System	29 Oct 2020 12:34:42
	System	29 Oct 2020 12:34:42

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:40:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-29T08:34:27', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '85cc7805-4109-4e27-8886-a5b913c80ad9' User entered 'None (0)'	System	29 Oct 2020 12:34:42
	System	29 Oct 2020 12:34:42



US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:40:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-29T08:34:28', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '85cc7805-4109-4e27-8886-a5b913c80ad9' User entered 'None (0)'	System	29 Oct 2020 12:34:42
	System	29 Oct 2020 12:34:42

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:40:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-29T08:34:30', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '85cc7805-4109-4e27-8886-a5b913c80ad9' User entered 'None (0)'	System	29 Oct 2020 12:34:42
	System	29 Oct 2020 12:34:42

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:40:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-29T08:34:31', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '85cc7805-4109-4e27-8886-a5b913c80ad9' User entered 'None (0)'	System	29 Oct 2020 12:34:42
	System	29 Oct 2020 12:34:42

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:40:32

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-29T08:34:33', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '85cc7805-4109-4e27-8886-a5b913c80ad9' User entered 'None (0)'	System	29 Oct 2020 12:34:42
	System	29 Oct 2020 12:34:42

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-29T08:34:34', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '85cc7805-4109-4e27-8886-a5b913c80ad9' User entered 'No (N)'	System	29 Oct 2020 12:34:42
	System	29 Oct 2020 12:34:42

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:40:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-10-29T08:34:41', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '85cc7805-4109-4e27-8886-a5b913c80ad9' User entered '29 Oct 2020 08:34'	System	29 Oct 2020 12:34:42
	System	29 Oct 2020 12:34:42

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '28 Oct 2020 12:00'	System	22 Oct 2020 18:54:23

US3432641

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '29 Oct 2020 11:59'	System	22 Oct 2020 18:54:23



**US3432641**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:40:32**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 18:23:55

US3432641

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '30 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 18:23:55

US3432641

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	30 Oct 2020 18:23:55

US3432641

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:32

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 18:23:55

US3432641

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 18:24:03

**US3432641**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:40:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User entered 'l'	System	30 Oct 2020 18:24:03

**US3432641**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:40:32**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 15:09:24

**US3432641**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:40:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '6 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 15:09:24



**US3432641**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:40:32**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	06 Nov 2020 15:09:24

US3432641

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:32

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 15:09:24

US3432641

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 15:13:46

**US3432641**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:40:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:27:01
User entered 'l'	System	06 Nov 2020 15:13:46

US3432641

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:56:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	Megan Powell (b) (4)	12 Nov 2020 17:58:08

US3432641

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:56:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '12 Nov 2020'	Megan Powell (b) (4)	12 Nov 2020 17:58:08

US3432641

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:56:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Contact Made (CONTACT MADE)'	Megan Powell (b) (4)	12 Nov 2020 17:58:08

US3432641

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:32

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:56:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	Megan Powell (b) (4)	12 Nov 2020 17:58:08



US3432641

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:56:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 13:23:49

US3432641

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:56:11
User entered 'l'	System	13 Nov 2020 13:23:49

US3432641

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Nov 2020 19:23:35

US3432641

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '25 Nov 2020'	(b) (4), (b) (6)	25 Nov 2020 19:23:35

US3432641

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:32

[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 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	25 Nov 2020 19:23:35

US3432641

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User entered 'VISIT2'	System	25 Nov 2020 19:23:35

US3432641

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	25 Nov 2020 20:02:41

US3432641

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Nov 2020 20:02:41



US3432641

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '25 Nov 2020'	(b) (4), (b) (6)	25 Nov 2020 20:02:41

US3432641

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '13:26'	(b) (4), (b) (6)	25 Nov 2020 20:02:41

US3432641

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User entered '25 Nov 2020 13:26'	System	25 Nov 2020 20:02:41

US3432641

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '036.8' C	(b) (4), (b) (6)	25 Nov 2020 20:02:41

US3432641

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Oral (Oral)'	(b) (4), (b) (6)	25 Nov 2020 20:02:41

US3432641

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 20:02:41

US3432641

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '085'	(b) (4), (b) (6)	25 Nov 2020 20:02:41

US3432641

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User entered 'bpm'	System	25 Nov 2020 20:02:41



US3432641

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '016'	(b) (4), (b) (6)	25 Nov 2020 20:02:41

US3432641

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User entered 'breaths/min'	System	25 Nov 2020 20:02:41

US3432641

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '122'	(b) (4), (b) (6)	25 Nov 2020 20:02:41

US3432641

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User entered 'mmHg'	System	25 Nov 2020 20:02:41

US3432641

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '071'	(b) (4), (b) (6)	25 Nov 2020 20:02:41

US3432641

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:40:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User entered 'mmHg'	System	25 Nov 2020 20:02:41

US3432641

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	25 Nov 2020 20:02:41

US3432641

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Nov 2020 20:02:41



US3432641

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '25 Nov 2020'	(b) (4), (b) (6)	25 Nov 2020 20:02:41

US3432641

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '14:49'	(b) (4), (b) (6)	25 Nov 2020 20:02:41

US3432641

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User entered '25 Nov 2020 14:49'	System	25 Nov 2020 20:02:41

US3432641

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '036.9' C	(b) (4), (b) (6)	25 Nov 2020 20:02:41

US3432641

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Oral (Oral)'	(b) (4), (b) (6)	25 Nov 2020 20:02:41

US3432641

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 20:02:41

US3432641

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '076'	(b) (4), (b) (6)	25 Nov 2020 20:02:41

US3432641

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User entered 'bpm'	System	25 Nov 2020 20:02:41



US3432641

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '012'	(b) (4), (b) (6)	25 Nov 2020 20:02:41

US3432641

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User entered 'breaths/min'	System	25 Nov 2020 20:02:41

US3432641

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '110'	(b) (4), (b) (6)	25 Nov 2020 20:02:41

US3432641

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User entered 'mmHg'	System	25 Nov 2020 20:02:41

US3432641

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '072'	(b) (4), (b) (6)	25 Nov 2020 20:02:41

US3432641

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:40:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User entered 'mmHg'	System	25 Nov 2020 20:02:41

US3432641

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:40:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Nov 2020 19:24:28

US3432641

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:40:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '25 Nov 2020'	(b) (4), (b) (6)	25 Nov 2020 19:24:28



US3432641

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:40:32

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Nov 2020 19:24:20

US3432641

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:40:32

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '25 Nov 2020'	(b) (4), (b) (6)	25 Nov 2020 19:24:20

US3432641

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:40:32

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Urine (URINE)'	(b) (4), (b) (6)	25 Nov 2020 19:24:20

US3432641

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:40:32

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	25 Nov 2020 19:24:20

US3432641

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:40:32

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'No (N)'	(b) (4), (b) (6)	25 Nov 2020 19:24:20

**US3432641**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:40:32**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 19:24:20

US3432641

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:40:32

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 19:24:20

US3432641

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:40:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User entered empty.	System	25 Nov 2020 19:24:20



US3432641

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:40:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Nov 2020 19:24:00

US3432641

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:40:32

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 19:24:00

US3432641

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 19:24:00

US3432641

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:40:32

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User entered 'MRNA-1273 OR PLACEBO'	System	25 Nov 2020 19:24:00

US3432641

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:40:32

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '25 Nov 2020'	(b) (4), (b) (6)	25 Nov 2020 19:24:00

US3432641

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:40:32

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '14:19'	(b) (4), (b) (6)	25 Nov 2020 19:24:00

US3432641

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:40:32

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User entered '25 Nov 2020 14:19'	System	25 Nov 2020 19:24:00

US3432641

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:40:32

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	25 Nov 2020 19:24:00



US3432641

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:40:32

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User entered 'ONCE'	System	25 Nov 2020 19:24:00

US3432641

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:40:32

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User entered 'INTRAMUSCULAR'	System	25 Nov 2020 19:24:00

US3432641

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Nov 2020 19:47:11

US3432641

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:32

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '25 Nov 2020'	(b) (4), (b) (6)	25 Nov 2020 19:47:11

US3432641

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '13:52'	(b) (4), (b) (6)	25 Nov 2020 19:47:11

US3432641

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User entered '25 Nov 2020 13:52'	System	25 Nov 2020 19:47:11

US3432641

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:40:32

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '25 Nov 2020'	(b) (4), (b) (6)	25 Nov 2020 19:47:21

**US3432641**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:40:32**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	25 Nov 2020 19:47:21



US3432641

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:40:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Nov 2020 19:47:21

US3432641

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:40:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '13:55'	(b) (4), (b) (6)	25 Nov 2020 19:47:21

US3432641

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:40:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User entered '25 Nov 2020 13:55'	System	25 Nov 2020 19:47:21

US3432641

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:40:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	25 Nov 2020 19:47:21

US3432641

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:40:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'No (N)'	(b) (4), (b) (6)	25 Nov 2020 19:47:21

US3432641

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:40:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 19:47:21

US3432641

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:40:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User entered empty.	System	25 Nov 2020 19:47:21

US3432641

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Nov 2020 20:02:47



US3432641

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:29
User entered 'I'	System	25 Nov 2020 20:02:47

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	25 Nov 2020 19:24:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-25T14:54:38', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'e712e953-b2a1-4060-a0bd-4433fe4a090c' User entered 'Yes (Y)'	System	25 Nov 2020 19:54:56
	System	25 Nov 2020 19:54:56

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-25T14:54:47', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'e712e953-b2a1-4060-a0bd-4433fe4a090c' User entered '98.5'	System	25 Nov 2020 19:54:56
	System	25 Nov 2020 19:54:56

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-25T14:54:51', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'e712e953-b2a1-4060-a0bd-4433fe4a090c' User entered 'No (N)'	System	25 Nov 2020 19:54:56
	System	25 Nov 2020 19:54:56

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-25T14:54:53', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'e712e953-b2a1-4060-a0bd-4433fe4a090c' User entered '25 Nov 2020 14:54'	System	25 Nov 2020 19:54:56
	System	25 Nov 2020 19:54:56

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '25 Nov 2020 14:39'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '25 Nov 2020 17:09'	System	25 Nov 2020 19:24:00



US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	25 Nov 2020 19:24:00
User entered 'Day 1, after vaccination (at home)'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-25T19:02:07', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'c0738934-8efa-4ea1-a80b-1aa42772e813' User entered 'Yes (Y)'	System	26 Nov 2020 00:02:31
	System	26 Nov 2020 00:02:31

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-25T19:02:13', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'c0738934-8efa-4ea1-a80b-1aa42772e813' User entered '98.2'	System	26 Nov 2020 00:02:31
	System	26 Nov 2020 00:02:31

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-25T19:02:19', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'c0738934-8efa-4ea1-a80b-1aa42772e813' User entered 'Yes (Y)'	System	26 Nov 2020 00:02:31
	System	26 Nov 2020 00:02:31

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
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 07:19:27
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-25T19:02:24', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'c0738934-8efa-4ea1-a80b-1aa42772e813' User entered '1'	Phoebe Cunningham (b) (4)	04 Dec 2020 20:10:13
	System	26 Nov 2020 00:02:31
	System	26 Nov 2020 00:02:31
	System	26 Nov 2020 00:02:31

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-25T19:02:24', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'c0738934-8efa-4ea1-a80b-1aa42772e813' User entered '0'	System	26 Nov 2020 00:02:31
	System	26 Nov 2020 00:02:31

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-25T19:02:27', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'c0738934-8efa-4ea1-a80b-1aa42772e813' User entered '25 Nov 2020 19:02'	System	26 Nov 2020 00:02:31
	System	26 Nov 2020 00:02:31

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '25 Nov 2020 18:04'	System	25 Nov 2020 19:24:00



US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '26 Nov 2020 11:59'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	25 Nov 2020 19:24:00
User entered 'Day 2'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:40:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-27T07:26:52', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '625f020f-410b-4f64-90f9-354cec41456a' User entered 'Yes (Y)'	System	27 Nov 2020 12:27:10
	System	27 Nov 2020 12:27:10

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:40:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-27T07:26:57', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '625f020f-410b-4f64-90f9-354cec41456a' User entered '98.5'	System	27 Nov 2020 12:27:10
	System	27 Nov 2020 12:27:10

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-27T07:27:02', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '625f020f-410b-4f64-90f9-354cec41456a' User entered 'Yes (Y)'	System	27 Nov 2020 12:27:10
	System	27 Nov 2020 12:27:10

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
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 07:19:49
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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-27T07:27:05', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '625f020f-410b-4f64-90f9-354cec41456a' User entered '1'	Phoebe Cunningham (b) (4)	04 Dec 2020 20:10:20
	System	27 Nov 2020 12:27:10
	System	27 Nov 2020 12:27:10
	System	27 Nov 2020 12:27:10

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:40:32

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-27T07:27:05', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '625f020f-410b-4f64-90f9-354cec41456a' User entered '0'	System	27 Nov 2020 12:27:10
	System	27 Nov 2020 12:27:10

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:40:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-27T07:27:08', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '625f020f-410b-4f64-90f9-354cec41456a' User entered '27 Nov 2020 07:27'	System	27 Nov 2020 12:27:10
	System	27 Nov 2020 12:27:10



US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '26 Nov 2020 12:00'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '27 Nov 2020 11:59'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	25 Nov 2020 19:24:00
User entered 'Day 3'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:40:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-28T07:39:11', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '72493dca-cb47-4292-8b51-0ae0fc0088a3' User entered 'Yes (Y)'	System	28 Nov 2020 12:39:28
	System	28 Nov 2020 12:39:28

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:40:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-28T07:39:16', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '72493dca-cb47-4292-8b51-0ae0fc0088a3' User entered '98.5'	System	28 Nov 2020 12:39:28
	System	28 Nov 2020 12:39:28

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-28T07:39:19', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '72493dca-cb47-4292-8b51-0ae0fc0088a3'	System	28 Nov 2020 12:39:28
User entered 'No (N)'	System	28 Nov 2020 12:39:28

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:40:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-28T07:39:25', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '72493dca-cb47-4292-8b51-0ae0fc0088a3' User entered '28 Nov 2020 07:39'	System	28 Nov 2020 12:39:28
	System	28 Nov 2020 12:39:28

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '27 Nov 2020 12:00'	System	25 Nov 2020 19:24:00



US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '28 Nov 2020 11:59'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	25 Nov 2020 19:24:00
User entered 'Day 4'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:40:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-29T09:14:44', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '0a0c66b2-a87b-4ff7-b2eb-a5841e7270ae' User entered 'Yes (Y)'	System	29 Nov 2020 14:14:56
	System	29 Nov 2020 14:14:56

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:40:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-29T09:14:48', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '0a0c66b2-a87b-4ff7-b2eb-a5841e7270ae' User entered '98.5'	System	29 Nov 2020 14:14:56
	System	29 Nov 2020 14:14:56

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-29T09:14:51', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '0a0c66b2-a87b-4ff7-b2eb-a5841e7270ae' User entered 'No (N)'	System	29 Nov 2020 14:14:56
	System	29 Nov 2020 14:14:56

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:40:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-29T09:14:53', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '0a0c66b2-a87b-4ff7-b2eb-a5841e7270ae' User entered '29 Nov 2020 09:14'	System	29 Nov 2020 14:14:56
	System	29 Nov 2020 14:14:56

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '28 Nov 2020 12:00'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '29 Nov 2020 11:59'	System	25 Nov 2020 19:24:00



US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	25 Nov 2020 19:24:00
User entered 'Day 5'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:40:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-30T09:35:13', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '50c1a216-caad-4fa8-acf4-cee050731201' User entered 'Yes (Y)'	System	30 Nov 2020 14:35:27
	System	30 Nov 2020 14:35:27

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:40:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-30T09:35:19', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '50c1a216-caad-4fa8-acf4-cee050731201' User entered '97.5'	System	30 Nov 2020 14:35:27
	System	30 Nov 2020 14:35:27

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-30T09:35:22', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '50c1a216-caad-4fa8-acf4-cee050731201' User entered 'No (N)'	System	30 Nov 2020 14:35:27
	System	30 Nov 2020 14:35:27

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:40:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-30T09:35:25', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '50c1a216-caad-4fa8-acf4-cee050731201' User entered '30 Nov 2020 09:35'	System	30 Nov 2020 14:35:27
	System	30 Nov 2020 14:35:27

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '29 Nov 2020 12:00'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '30 Nov 2020 11:59'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	25 Nov 2020 19:24:00
User entered 'Day 6'	System	25 Nov 2020 19:24:00



US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:40:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-01T10:12:02', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'be98b787-ca91-499c-b0b8-445c8125926a' User entered 'Yes (Y)'	System	01 Dec 2020 15:12:14
	System	01 Dec 2020 15:12:14

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:40:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-01T10:12:07', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'be98b787-ca91-499c-b0b8-445c8125926a' User entered '98.2'	System	01 Dec 2020 15:12:14
	System	01 Dec 2020 15:12:14

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-01T10:12:09', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'be98b787-ca91-499c-b0b8-445c8125926a' User entered 'No (N)'	System	01 Dec 2020 15:12:14
	System	01 Dec 2020 15:12:14

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:40:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-01T10:12:11', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'be98b787-ca91-499c-b0b8-445c8125926a' User entered '01 Dec 2020 10:12'	System	01 Dec 2020 15:12:14
	System	01 Dec 2020 15:12:14

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '30 Nov 2020 12:00'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '01 Dec 2020 11:59'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	25 Nov 2020 19:24:00
User entered 'Day 7'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:40:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-02T10:11:20', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'fc98d63b-dd0f-4125-a2c8-f39a3a942508' User entered 'Yes (Y)'	System	02 Dec 2020 15:11:31
	System	02 Dec 2020 15:11:31



US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:40:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-02T10:11:23', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'fc98d63b-dd0f-4125-a2c8-f39a3a942508' User entered '98.5'	System	02 Dec 2020 15:11:31
	System	02 Dec 2020 15:11:31

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-02T10:11:25', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'fc98d63b-dd0f-4125-a2c8-f39a3a942508'	System	02 Dec 2020 15:11:31
User entered 'No (N)'	System	02 Dec 2020 15:11:31

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:40:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-02T10:11:27', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'fc98d63b-dd0f-4125-a2c8-f39a3a942508' User entered '02 Dec 2020 10:11'	System	02 Dec 2020 15:11:31
	System	02 Dec 2020 15:11:31

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '01 Dec 2020 12:00'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '02 Dec 2020 11:59'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	25 Nov 2020 19:24:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-25T14:55:01', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '6f45a8ae-f5c5-45c3-8b37-ac7c6b3e68bb' User entered 'None (1)'	System	25 Nov 2020 19:55:19
	System	25 Nov 2020 19:55:19

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-25T14:55:04', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '6f45a8ae-f5c5-45c3-8b37-ac7c6b3e68bb' User entered 'No (N)'	System	25 Nov 2020 19:55:19
	System	25 Nov 2020 19:55:19



US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-25T14:55:08', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '6f45a8ae-f5c5-45c3-8b37-ac7c6b3e68bb' User entered 'No (N)'	System	25 Nov 2020 19:55:19
	System	25 Nov 2020 19:55:19

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-25T14:55:11', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '6f45a8ae-f5c5-45c3-8b37-ac7c6b3e68bb'	System	25 Nov 2020 19:55:19
User entered 'None (1)'	System	25 Nov 2020 19:55:19

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-25T14:55:14', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '6f45a8ae-f5c5-45c3-8b37-ac7c6b3e68bb' User entered '25 Nov 2020 14:55'	System	25 Nov 2020 19:55:19
	System	25 Nov 2020 19:55:19

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '25 Nov 2020 14:39'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '25 Nov 2020 17:09'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	25 Nov 2020 19:24:00
User entered 'Day 1, after vaccination (at home)'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-25T19:02:34', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '8319ebcd-3332-4730-8529-f5af01a5dcb8'	System	26 Nov 2020 00:04:16
User entered 'Does not interfere with activity (2)'	System	26 Nov 2020 00:04:16

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-25T19:02:36', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '8319ebcd-3332-4730-8529-f5af01a5dcb8' User entered 'No (N)'	System	26 Nov 2020 00:04:16
	System	26 Nov 2020 00:04:16



US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-25T19:04:03', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '8319ebcd-3332-4730-8529-f5af01a5dcb8' User entered 'No (N)'	System	26 Nov 2020 00:04:16
	System	26 Nov 2020 00:04:16

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-25T19:04:10', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '8319ebcd-3332-4730-8529-f5af01a5dcb8'	System	26 Nov 2020 00:04:16
User entered 'None (1)'	System	26 Nov 2020 00:04:16

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-25T19:04:14', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '8319ebcd-3332-4730-8529-f5af01a5dcb8' User entered '25 Nov 2020 19:04'	System	26 Nov 2020 00:04:16
	System	26 Nov 2020 00:04:16

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '25 Nov 2020 18:04'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '26 Nov 2020 11:59'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	25 Nov 2020 19:24:00
User entered 'Day 2'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-27T07:27:14', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'a585bf7c-cbdc-4fab-870a-578875fc98fc'	System	27 Nov 2020 12:27:24
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	27 Nov 2020 12:27:24

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:40:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-27T07:27:16', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'a585bf7c-cbdc-4fab-870a-578875fc98fc' User entered 'No (N)'	System	27 Nov 2020 12:27:24
	System	27 Nov 2020 12:27:24



US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-27T07:27:18', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'a585bf7c-cbdc-4fab-870a-578875fc98fc' User entered 'No (N)'	System	27 Nov 2020 12:27:24
	System	27 Nov 2020 12:27:24

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-27T07:27:20', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'a585bf7c-cbdc-4fab-870a-578875fc98fc' User entered 'None (1)'	System	27 Nov 2020 12:27:24
	System	27 Nov 2020 12:27:24

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:40:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-27T07:27:22', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'a585bf7c-cbdc-4fab-870a-578875fc98fc' User entered '27 Nov 2020 07:27'	System	27 Nov 2020 12:27:24
	System	27 Nov 2020 12:27:24

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '26 Nov 2020 12:00'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '27 Nov 2020 11:59'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	25 Nov 2020 19:24:00
User entered 'Day 3'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-28T07:39:31', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'c616e93a-b2d8-45aa-af02-7f7a77f0d347'	System	28 Nov 2020 12:39:57
User entered 'Does not interfere with activity (2)'	System	28 Nov 2020 12:39:57

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:40:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-28T07:39:34', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'c616e93a-b2d8-45aa-af02-7f7a77f0d347' User entered 'No (N)'	System	28 Nov 2020 12:39:57
	System	28 Nov 2020 12:39:57



US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-28T07:39:45', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'c616e93a-b2d8-45aa-af02-7f7a77f0d347' User entered 'No (N)'	System	28 Nov 2020 12:39:57
	System	28 Nov 2020 12:39:57

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-28T07:39:50', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'c616e93a-b2d8-45aa-af02-7f7a77f0d347'	System	28 Nov 2020 12:39:57
User entered 'None (1)'	System	28 Nov 2020 12:39:57

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:40:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-28T07:39:55', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'c616e93a-b2d8-45aa-af02-7f7a77f0d347' User entered '28 Nov 2020 07:39'	System	28 Nov 2020 12:39:57
	System	28 Nov 2020 12:39:57

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '27 Nov 2020 12:00'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '28 Nov 2020 11:59'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	25 Nov 2020 19:24:00
User entered 'Day 4'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-29T09:15:10', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '84b95e1d-e266-45de-bf9d-602f2658789b' User entered 'None (1)'	System	29 Nov 2020 14:15:29
	System	29 Nov 2020 14:15:29

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:40:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-29T09:15:13', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '84b95e1d-e266-45de-bf9d-602f2658789b' User entered 'No (N)'	System	29 Nov 2020 14:15:29
	System	29 Nov 2020 14:15:29



US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-29T09:15:17', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '84b95e1d-e266-45de-bf9d-602f2658789b' User entered 'No (N)'	System	29 Nov 2020 14:15:29
	System	29 Nov 2020 14:15:29

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-29T09:15:19', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '84b95e1d-e266-45de-bf9d-602f2658789b' User entered 'None (1)'	System	29 Nov 2020 14:15:29
	System	29 Nov 2020 14:15:29

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:40:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-29T09:15:22', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '84b95e1d-e266-45de-bf9d-602f2658789b' User entered '29 Nov 2020 09:15'	System	29 Nov 2020 14:15:29
	System	29 Nov 2020 14:15:29

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '28 Nov 2020 12:00'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '29 Nov 2020 11:59'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	25 Nov 2020 19:24:00
User entered 'Day 5'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-30T09:35:40', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '2fdd367e-d3eb-4f1d-a182-1ae6c6d6095e' User entered 'None (1)'	System	30 Nov 2020 14:36:01
	System	30 Nov 2020 14:36:01

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:40:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-30T09:35:43', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '2fdd367e-d3eb-4f1d-a182-1ae6c6d6095e' User entered 'No (N)'	System	30 Nov 2020 14:36:01
	System	30 Nov 2020 14:36:01



US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-30T09:35:45', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '2fdd367e-d3eb-4f1d-a182-1ae6c6d6095e' User entered 'No (N)'	System	30 Nov 2020 14:36:01
	System	30 Nov 2020 14:36:01

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-30T09:35:54', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '2fdd367e-d3eb-4f1d-a182-1ae6c6d6095e' User entered 'None (1)'	System	30 Nov 2020 14:36:01
	System	30 Nov 2020 14:36:01

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:40:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-30T09:35:56', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '2fdd367e-d3eb-4f1d-a182-1ae6c6d6095e' User entered '30 Nov 2020 09:35'	System	30 Nov 2020 14:36:01
	System	30 Nov 2020 14:36:01

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '29 Nov 2020 12:00'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '30 Nov 2020 11:59'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	25 Nov 2020 19:24:00
User entered 'Day 6'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-01T10:12:14', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'ce462abc-7b65-44e1-802f-b92cf0ac9f56'	System	01 Dec 2020 15:12:35
User entered 'None (1)'	System	01 Dec 2020 15:12:35

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:40:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-01T10:12:17', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'ce462abc-7b65-44e1-802f-b92cf0ac9f56' User entered 'No (N)'	System	01 Dec 2020 15:12:35
	System	01 Dec 2020 15:12:35



US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-01T10:12:19', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'ce462abc-7b65-44e1-802f-b92cf0ac9f56' User entered 'No (N)'	System	01 Dec 2020 15:12:35
	System	01 Dec 2020 15:12:35

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-01T10:12:21', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'ce462abc-7b65-44e1-802f-b92cf0ac9f56'	System	01 Dec 2020 15:12:35
User entered 'None (1)'	System	01 Dec 2020 15:12:35

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:40:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-01T10:12:31', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'ce462abc-7b65-44e1-802f-b92cf0ac9f56' User entered '01 Dec 2020 10:12'	System	01 Dec 2020 15:12:35
	System	01 Dec 2020 15:12:35

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '30 Nov 2020 12:00'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '01 Dec 2020 11:59'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	25 Nov 2020 19:24:00
User entered 'Day 7'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-02T10:11:30', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '24ddd564-dbc3-4d50-aa82-e310bd8c18f3'	System	02 Dec 2020 15:11:39
User entered 'None (1)'	System	02 Dec 2020 15:11:39

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:40:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-02T10:11:32', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '24ddd564-dbc3-4d50-aa82-e310bd8c18f3' User entered 'No (N)'	System	02 Dec 2020 15:11:39
	System	02 Dec 2020 15:11:39



US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-02T10:11:33', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '24ddd564-dbc3-4d50-aa82-e310bd8c18f3' User entered 'No (N)'	System	02 Dec 2020 15:11:39
	System	02 Dec 2020 15:11:39

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-02T10:11:34', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '24ddd564-dbc3-4d50-aa82-e310bd8c18f3' User entered 'None (1)'	System	02 Dec 2020 15:11:39
	System	02 Dec 2020 15:11:39

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:40:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-02T10:11:37', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '24ddd564-dbc3-4d50-aa82-e310bd8c18f3' User entered '02 Dec 2020 10:11'	System	02 Dec 2020 15:11:39
	System	02 Dec 2020 15:11:39

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '01 Dec 2020 12:00'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '02 Dec 2020 11:59'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	25 Nov 2020 19:24:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-25T14:55:22', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '626e79d2-2361-49a4-af5f-55ef62dc8892'	System	25 Nov 2020 19:55:44
User entered 'No interference with activity (1)'	System	25 Nov 2020 19:55:44

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-25T14:55:26', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '626e79d2-2361-49a4-af5f-55ef62dc8892'	System	25 Nov 2020 19:55:44
User entered 'None (0)'	System	25 Nov 2020 19:55:44



US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-25T14:55:28', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '626e79d2-2361-49a4-af5f-55ef62dc8892' User entered 'None (0)'	System	25 Nov 2020 19:55:44
	System	25 Nov 2020 19:55:44

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-25T14:55:31', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '626e79d2-2361-49a4-af5f-55ef62dc8892' User entered 'None (0)'	System	25 Nov 2020 19:55:44
	System	25 Nov 2020 19:55:44

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-25T14:55:34', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '626e79d2-2361-49a4-af5f-55ef62dc8892' User entered 'None (0)'	System	25 Nov 2020 19:55:44
	System	25 Nov 2020 19:55:44

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-25T14:55:36', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '626e79d2-2361-49a4-af5f-55ef62dc8892' User entered 'None (0)'	System	25 Nov 2020 19:55:44
	System	25 Nov 2020 19:55:44

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-25T14:55:39', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '626e79d2-2361-49a4-af5f-55ef62dc8892'	System	25 Nov 2020 19:55:44
User entered 'No (N)'	System	25 Nov 2020 19:55:44

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-25T14:55:42', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '626e79d2-2361-49a4-af5f-55ef62dc8892'	System	25 Nov 2020 19:55:44
User entered '25 Nov 2020 14:55'	System	25 Nov 2020 19:55:44

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '25 Nov 2020 14:39'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '25 Nov 2020 17:09'	System	25 Nov 2020 19:24:00



US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	25 Nov 2020 19:24:00
User entered 'Day 1, after vaccination (at home)'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-25T19:04:18', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '4bb9bf9f-6486-44d0-92c0-8a83420a4d29'	System	26 Nov 2020 00:04:43
User entered 'No interference with activity (1)'	System	26 Nov 2020 00:04:43

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-25T19:04:23', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '4bb9bf9f-6486-44d0-92c0-8a83420a4d29'	System	26 Nov 2020 00:04:43
User entered 'No interference with activity (1)'	System	26 Nov 2020 00:04:43

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-25T19:04:26', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '4bb9bf9f-6486-44d0-92c0-8a83420a4d29' User entered 'None (0)'	System	26 Nov 2020 00:04:43
	System	26 Nov 2020 00:04:43

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-25T19:04:28', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '4bb9bf9f-6486-44d0-92c0-8a83420a4d29' User entered 'None (0)'	System	26 Nov 2020 00:04:43
	System	26 Nov 2020 00:04:43

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-25T19:04:31', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '4bb9bf9f-6486-44d0-92c0-8a83420a4d29'	System	26 Nov 2020 00:04:43
User entered 'None (0)'	System	26 Nov 2020 00:04:43

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-25T19:04:34', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '4bb9bf9f-6486-44d0-92c0-8a83420a4d29' User entered 'None (0)'	System	26 Nov 2020 00:04:43
	System	26 Nov 2020 00:04:43

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-25T19:04:37', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '4bb9bf9f-6486-44d0-92c0-8a83420a4d29'	System	26 Nov 2020 00:04:43
User entered 'No (N)'	System	26 Nov 2020 00:04:43



US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-25T19:04:40', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '4bb9bf9f-6486-44d0-92c0-8a83420a4d29' User entered '25 Nov 2020 19:04'	System	26 Nov 2020 00:04:43
	System	26 Nov 2020 00:04:43

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '25 Nov 2020 18:04'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '26 Nov 2020 11:59'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	25 Nov 2020 19:24:00
User entered 'Day 2'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:40:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-27T07:27:26', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '2d421637-57fe-4cd1-b4ff-985202c80d28'	System	27 Nov 2020 12:27:51
User entered 'No interference with activity (1)'	System	27 Nov 2020 12:27:51

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:40:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-27T07:27:31', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '2d421637-57fe-4cd1-b4ff-985202c80d28'	System	27 Nov 2020 12:27:51
User entered 'No interference with activity (1)'	System	27 Nov 2020 12:27:51

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:40:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-27T07:27:35', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '2d421637-57fe-4cd1-b4ff-985202c80d28' User entered 'Some interference with activity (2)'	System	27 Nov 2020 12:27:51
	System	27 Nov 2020 12:27:51

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:40:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-27T07:27:40', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '2d421637-57fe-4cd1-b4ff-985202c80d28' User entered 'None (0)'	System	27 Nov 2020 12:27:51
	System	27 Nov 2020 12:27:51



US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:40:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-27T07:27:42', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '2d421637-57fe-4cd1-b4ff-985202c80d28'	System	27 Nov 2020 12:27:51
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	27 Nov 2020 12:27:51

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:40:32

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-27T07:27:44', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '2d421637-57fe-4cd1-b4ff-985202c80d28' User entered 'None (0)'	System	27 Nov 2020 12:27:51
	System	27 Nov 2020 12:27:51

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-27T07:27:45', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '2d421637-57fe-4cd1-b4ff-985202c80d28' User entered 'No (N)'	System	27 Nov 2020 12:27:51
	System	27 Nov 2020 12:27:51

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:40:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-27T07:27:48', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '2d421637-57fe-4cd1-b4ff-985202c80d28' User entered '27 Nov 2020 07:27'	System	27 Nov 2020 12:27:51
	System	27 Nov 2020 12:27:51

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '26 Nov 2020 12:00'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '27 Nov 2020 11:59'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	25 Nov 2020 19:24:00
User entered 'Day 3'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:40:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-28T07:39:59', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'ed79ae42-b02e-460c-bfe5-31b1b2655819'	System	28 Nov 2020 12:40:25
User entered 'No interference with activity (1)'	System	28 Nov 2020 12:40:25



US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:40:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-28T07:40:02', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'ed79ae42-b02e-460c-bfe5-31b1b2655819'	System	28 Nov 2020 12:40:25
User entered 'No interference with activity (1)'	System	28 Nov 2020 12:40:25

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:40:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-28T07:40:09', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'ed79ae42-b02e-460c-bfe5-31b1b2655819'	System	28 Nov 2020 12:40:25
User entered 'No interference with activity (1)'	System	28 Nov 2020 12:40:25

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:40:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-28T07:40:13', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'ed79ae42-b02e-460c-bfe5-31b1b2655819'	System	28 Nov 2020 12:40:25
User entered 'No interference with activity (1)'	System	28 Nov 2020 12:40:25

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:40:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-28T07:40:15', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'ed79ae42-b02e-460c-bfe5-31b1b2655819' User entered 'None (0)'	System	28 Nov 2020 12:40:25
	System	28 Nov 2020 12:40:25

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:40:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-28T07:40:17', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'ed79ae42-b02e-460c-bfe5-31b1b2655819' User entered 'None (0)'	System	28 Nov 2020 12:40:25
	System	28 Nov 2020 12:40:25

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-28T07:40:20', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'ed79ae42-b02e-460c-bfe5-31b1b2655819' User entered 'No (N)'	System	28 Nov 2020 12:40:25
	System	28 Nov 2020 12:40:25

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:40:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-28T07:40:23', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'ed79ae42-b02e-460c-bfe5-31b1b2655819' User entered '28 Nov 2020 07:40'	System	28 Nov 2020 12:40:25
	System	28 Nov 2020 12:40:25

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '27 Nov 2020 12:00'	System	25 Nov 2020 19:24:00



US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '28 Nov 2020 11:59'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	25 Nov 2020 19:24:00
User entered 'Day 4'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:40:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-29T09:15:25', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '261ba86a-5b28-4377-8c56-d4b70b29f17f' User entered 'None (0)'	System	29 Nov 2020 14:15:47
	System	29 Nov 2020 14:15:47

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:40:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-29T09:15:26', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '261ba86a-5b28-4377-8c56-d4b70b29f17f' User entered 'None (0)'	System	29 Nov 2020 14:15:47
	System	29 Nov 2020 14:15:47

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:40:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-29T09:15:29', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '261ba86a-5b28-4377-8c56-d4b70b29f17f' User entered 'None (0)'	System	29 Nov 2020 14:15:47
	System	29 Nov 2020 14:15:47

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:40:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-29T09:15:32', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '261ba86a-5b28-4377-8c56-d4b70b29f17f' User entered 'None (0)'	System	29 Nov 2020 14:15:47
	System	29 Nov 2020 14:15:47

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:40:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-29T09:15:34', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '261ba86a-5b28-4377-8c56-d4b70b29f17f' User entered 'None (0)'	System	29 Nov 2020 14:15:47
	System	29 Nov 2020 14:15:47

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:40:32

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-29T09:15:36', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '261ba86a-5b28-4377-8c56-d4b70b29f17f' User entered 'None (0)'	System	29 Nov 2020 14:15:47
	System	29 Nov 2020 14:15:47



US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-29T09:15:41', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '261ba86a-5b28-4377-8c56-d4b70b29f17f' User entered 'No (N)'	System	29 Nov 2020 14:15:47
	System	29 Nov 2020 14:15:47

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:40:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-29T09:15:43', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '261ba86a-5b28-4377-8c56-d4b70b29f17f' User entered '29 Nov 2020 09:15'	System	29 Nov 2020 14:15:47
	System	29 Nov 2020 14:15:47

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '28 Nov 2020 12:00'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '29 Nov 2020 11:59'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	25 Nov 2020 19:24:00
User entered 'Day 5'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:40:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-30T09:36:00', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '0eb3e672-db68-4250-bfb8-c7cbb830f2e9'	System	30 Nov 2020 14:36:24
User entered 'No interference with activity (1)'	System	30 Nov 2020 14:36:24

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:40:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-30T09:36:03', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '0eb3e672-db68-4250-bfb8-c7cbb830f2e9' User entered 'None (0)'	System	30 Nov 2020 14:36:24
	System	30 Nov 2020 14:36:24

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:40:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-30T09:36:06', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '0eb3e672-db68-4250-bfb8-c7cbb830f2e9' User entered 'None (0)'	System	30 Nov 2020 14:36:24
	System	30 Nov 2020 14:36:24



US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:40:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-30T09:36:14', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '0eb3e672-db68-4250-bfb8-c7cbb830f2e9' User entered 'None (0)'	System	30 Nov 2020 14:36:24
	System	30 Nov 2020 14:36:24

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:40:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-30T09:36:16', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '0eb3e672-db68-4250-bfb8-c7cbb830f2e9' User entered 'None (0)'	System	30 Nov 2020 14:36:24
	System	30 Nov 2020 14:36:24

**US3432641**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:40:32**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-30T09:36:17', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '0eb3e672-db68-4250-bfb8-c7cbb830f2e9' User entered 'None (0)'	System	30 Nov 2020 14:36:24
	System	30 Nov 2020 14:36:24

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-30T09:36:19', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '0eb3e672-db68-4250-bfb8-c7cbb830f2e9' User entered 'No (N)'	System	30 Nov 2020 14:36:24
	System	30 Nov 2020 14:36:24

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:40:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-11-30T09:36:21', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '0eb3e672-db68-4250-bfb8-c7cbb830f2e9' User entered '30 Nov 2020 09:36'	System	30 Nov 2020 14:36:24
	System	30 Nov 2020 14:36:24

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '29 Nov 2020 12:00'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '30 Nov 2020 11:59'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	25 Nov 2020 19:24:00
User entered 'Day 6'	System	25 Nov 2020 19:24:00



US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:40:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-01T10:12:35', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '1283536b-34ac-4701-a5e5-aca01dcc577d' User entered 'None (0)'	System	01 Dec 2020 15:12:49
	System	01 Dec 2020 15:12:49

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:40:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-01T10:12:37', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '1283536b-34ac-4701-a5e5-aca01dcc577d' User entered 'None (0)'	System	01 Dec 2020 15:12:49
	System	01 Dec 2020 15:12:49

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:40:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-01T10:12:38', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '1283536b-34ac-4701-a5e5-aca01dcc577d' User entered 'None (0)'	System	01 Dec 2020 15:12:49
	System	01 Dec 2020 15:12:49

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:40:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-01T10:12:40', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '1283536b-34ac-4701-a5e5-aca01dcc577d' User entered 'None (0)'	System	01 Dec 2020 15:12:49
	System	01 Dec 2020 15:12:49

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:40:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-01T10:12:42', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '1283536b-34ac-4701-a5e5-aca01dcc577d' User entered 'None (0)'	System	01 Dec 2020 15:12:49
	System	01 Dec 2020 15:12:49

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:40:32

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-01T10:12:43', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '1283536b-34ac-4701-a5e5-aca01dcc577d' User entered 'None (0)'	System	01 Dec 2020 15:12:49
	System	01 Dec 2020 15:12:49

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-01T10:12:45', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '1283536b-34ac-4701-a5e5-aca01dcc577d' User entered 'No (N)'	System	01 Dec 2020 15:12:49
	System	01 Dec 2020 15:12:49

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:40:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-01T10:12:47', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '1283536b-34ac-4701-a5e5-aca01dcc577d' User entered '01 Dec 2020 10:12'	System	01 Dec 2020 15:12:49
	System	01 Dec 2020 15:12:49



US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '30 Nov 2020 12:00'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '01 Dec 2020 11:59'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:40:32

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
Data entry locked.	System	25 Nov 2020 19:24:00
User entered 'Day 7'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:40:32

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-02T10:11:40', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '5d92f60f-ed72-47fb-bac1-22ec7cf77a08' User entered 'None (0)'	System	02 Dec 2020 15:11:54
	System	02 Dec 2020 15:11:54

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:40:32

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-02T10:11:41', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '5d92f60f-ed72-47fb-bac1-22ec7cf77a08' User entered 'None (0)'	System	02 Dec 2020 15:11:54
	System	02 Dec 2020 15:11:54

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:40:32

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-02T10:11:42', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '5d92f60f-ed72-47fb-bac1-22ec7cf77a08' User entered 'None (0)'	System	02 Dec 2020 15:11:54
	System	02 Dec 2020 15:11:54

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:40:32

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-02T10:11:43', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '5d92f60f-ed72-47fb-bac1-22ec7cf77a08' User entered 'None (0)'	System	02 Dec 2020 15:11:54
	System	02 Dec 2020 15:11:54

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:40:32

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-02T10:11:44', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '5d92f60f-ed72-47fb-bac1-22ec7cf77a08' User entered 'None (0)'	System	02 Dec 2020 15:11:54
	System	02 Dec 2020 15:11:54



US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:40:32

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-02T10:11:46', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '5d92f60f-ed72-47fb-bac1-22ec7cf77a08' User entered 'None (0)'	System	02 Dec 2020 15:11:54
	System	02 Dec 2020 15:11:54

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:40:32

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 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-02T10:11:47', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '5d92f60f-ed72-47fb-bac1-22ec7cf77a08'	System	02 Dec 2020 15:11:54
User entered 'No (N)'	System	02 Dec 2020 15:11:54

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:40:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-02T10:11:49', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '5d92f60f-ed72-47fb-bac1-22ec7cf77a08' User entered '02 Dec 2020 10:11'	System	02 Dec 2020 15:11:54
	System	02 Dec 2020 15:11:54

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:40:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '01 Dec 2020 12:00'	System	25 Nov 2020 19:24:00

US3432641

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:40:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:39:33
User entered '02 Dec 2020 11:59'	System	25 Nov 2020 19:24:00

US3432641

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	02 Dec 2020 21:07:52

US3432641

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:32

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '2 Dec 2020'	Kathleen Garvey (b) (4)	02 Dec 2020 21:07:52

US3432641

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Contact Made (CONTACT MADE)'	Kathleen Garvey (b) (4)	02 Dec 2020 21:07:52



US3432641

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:32

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	Kathleen Garvey (b) (4)	02 Dec 2020 21:07:52

US3432641

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	02 Dec 2020 21:07:58

US3432641

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User entered 'l'	System	02 Dec 2020 21:07:58

US3432641

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	10 Dec 2020 17:28:05

US3432641

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:32

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '10 Dec 2020'	Kathleen Garvey (b) (4)	10 Dec 2020 17:28:05

US3432641

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Contact Made (CONTACT MADE)'	Kathleen Garvey (b) (4)	10 Dec 2020 17:28:05

US3432641

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:32

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	Kathleen Garvey (b) (4)	10 Dec 2020 17:28:05

US3432641

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Dec 2020 17:28:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Dec 2020 17:28:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Kathleen Garvey (b) (4)	10 Dec 2020 17:28:19
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Dec 2020 17:28:12
User entered empty.	Kathleen Garvey (b) (4)	10 Dec 2020 17:28:12



**US3432641**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:40:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User entered 'l'	System	10 Dec 2020 17:28:19
User entered empty.	System	10 Dec 2020 17:28:12

**US3432641**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:40:32**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Dec 2020 14:46:59

US3432641

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '17 Dec 2020'	(b) (4), (b) (6)	17 Dec 2020 14:46:59

**US3432641**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:40:32**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Dec 2020 14:46:59

US3432641

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:32

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	(b) (4), (b) (6)	17 Dec 2020 14:46:59

US3432641

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Dec 2020 14:47:04

US3432641

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User entered 'l'	System	17 Dec 2020 14:47:04

US3432641

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:33
User entered 'Yes (Y)'	Austin Kim (b) (4)	08 Jan 2021 17:32:47



US3432641

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:32

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:33
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	15 Jan 2021 07:45:29
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'Pt no show'd for original appointment, combined OL-1 and v3' (Site from System).	Austin Kim (b) (4) (b) (4)	08 Jan 2021 17:33:34
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	08 Jan 2021 17:32:47
User entered '08 Jan 2021'	Austin Kim (b) (4) (b) (4)	08 Jan 2021 17:32:47

US3432641

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:33
User entered 'Clinic (Clinic)'	Austin Kim (b) (4) (b) (4)	08 Jan 2021 17:32:47

US3432641

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User entered 'VISIT3'	System	08 Jan 2021 17:32:47

US3432641

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:33
User entered 'Yes (Y)'	Austin Kim (b) (4)	08 Jan 2021 17:34:19

US3432641

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:33
User entered '08 Jan 2021'	Austin Kim (b) (4)	08 Jan 2021 17:34:19

**US3432641**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:40:32**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:33
User entered '10:42'	Austin Kim (b) (4) (b) (4)	08 Jan 2021 17:34:19

US3432641

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User entered '08 Jan 2021 10:42'	System	08 Jan 2021 17:34:19

US3432641

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:33
User entered '98.3' F	Austin Kim (b) (4)	08 Jan 2021 17:34:19



US3432641

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:33
User entered 'Oral (Oral)'	Austin Kim (b) (4)	08 Jan 2021 17:34:19

US3432641

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:33
User entered empty.	Austin Kim (b) (4)	08 Jan 2021 17:34:19

US3432641

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:33
User entered '81'	Austin Kim (b) (4)	08 Jan 2021 17:34:19

US3432641

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User entered 'bpm'	System	08 Jan 2021 17:34:19

US3432641

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:32

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:33
User entered '16'	Austin Kim (b) (4)	08 Jan 2021 17:34:19

US3432641

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User entered 'breaths/min'	System	08 Jan 2021 17:34:19

US3432641

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:33
User entered '120'	Austin Kim (b) (4)	08 Jan 2021 17:34:19

US3432641

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User entered 'mmHg'	System	08 Jan 2021 17:34:19



US3432641

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:33
User entered '84'	Austin Kim (b) (4)	08 Jan 2021 17:34:19

US3432641

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User entered 'mmHg'	System	08 Jan 2021 17:34:19

US3432641

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:32

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15

US3432641

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:40:32

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15

US3432641

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:40:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'No (N)'	Austin Kim (b) (4)	08 Jan 2021 17:34:30

US3432641

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:40:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	Austin Kim (b) (4)	08 Jan 2021 17:34:30

US3432641

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'Yes (Y)'	Austin Kim (b) (4)	08 Jan 2021 17:46:55

US3432641

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:32

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User closed query ' <input type="checkbox"/> Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 08JAN2021 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under OL-1 in PPD Central lab. Please reconcile and confirm the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 10:12:10
Query ' <input type="checkbox"/> Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 08JAN2021 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under OL-1 in PPD Central lab. Please reconcile and confirm the correct Visit and update if applicable. Else clarify, thank you.' answered with 'participant had a combined visit 3 and OL-1, this is why the lab req is the same' (Site from DM).	Austin Kim (b) (4)	24 Feb 2021 21:35:02
User opened query ' <input type="checkbox"/> Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 08JAN2021 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under OL-1 in PPD Central lab. Please reconcile and confirm the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 15:06:57
User entered '08 Jan 2021'	Austin Kim (b) (4)	08 Jan 2021 17:46:55



US3432641

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered '11:00'	Austin Kim (b) (4)	08 Jan 2021 17:46:55

US3432641

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User entered '08 Jan 2021 11:00'	System	08 Jan 2021 17:46:55

US3432641

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	Austin Kim (b) (4)	08 Jan 2021 17:47:01

US3432641

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User entered 'l'	System	08 Jan 2021 17:47:01

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-19T17:17:10', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '7c4f2a07-d394-4313-a818-982b67b9d229' User entered 'No (N)'	System	19 Dec 2020 22:17:16
	System	19 Dec 2020 22:17:16

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

Have you been exposed to someone with 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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-19T17:17:04', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '7c4f2a07-d394-4313-a818-982b67b9d229'	System	19 Dec 2020 22:17:16
User entered 'No (N)'	System	19 Dec 2020 22:17:16

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-19T17:17:14', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '7c4f2a07-d394-4313-a818-982b67b9d229' User entered '19 Dec 2020 17:17:14'	System	19 Dec 2020 22:17:16
	System	19 Dec 2020 22:17:16



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-27T17:52:00', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '3fc31991-5a43-4067-ad10-fc2f456628db' User entered 'No (N)'	System	27 Dec 2020 22:52:31

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

Have you been exposed to someone with 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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-27T17:52:05', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '3fc31991-5a43-4067-ad10-fc2f456628db' User entered 'No (N)'	System	27 Dec 2020 22:52:31

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2020-12-27T17:52:29', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '3fc31991-5a43-4067-ad10-fc2f456628db' User entered '27 Dec 2020 17:52:29'	System	27 Dec 2020 22:52:31

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 13:32:40



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-01-02T16:07:42', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '448606a9-92fe-4814-8161-36f1c3391470' User entered 'No (N)'	System	02 Jan 2021 21:08:06
	System	02 Jan 2021 21:08:06

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

Have you been exposed to someone with 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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-01-02T16:07:47', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '448606a9-92fe-4814-8161-36f1c3391470' User entered 'Yes (Y)'	System	02 Jan 2021 21:08:06
	System	02 Jan 2021 21:08:06

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Please 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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-01-02T16:07:52', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '448606a9-92fe-4814-8161-36f1c3391470'	System	02 Jan 2021 21:08:06
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Jan 2021 21:08:06

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-01-02T16:07:56', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '448606a9-92fe-4814-8161-36f1c3391470' User entered '02 Jan 2021 16:07:56'	System	02 Jan 2021 21:08:06
	System	02 Jan 2021 21:08:06

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 13:32:40



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-01-12T17:59:18', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '83678081-7aba-4309-9060-5077577af5d8' User entered 'No (N)'	System	12 Jan 2021 22:59:50

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

Have you been exposed to someone with 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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-01-12T17:59:35', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '83678081-7aba-4309-9060-5077577af5d8'	System	12 Jan 2021 22:59:50
User entered 'Yes (Y)'	System	12 Jan 2021 22:59:50

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Please 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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-01-12T17:59:37', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '83678081-7aba-4309-9060-5077577af5d8'	System	12 Jan 2021 22:59:50
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	12 Jan 2021 22:59:50

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-01-12T17:59:40', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '83678081-7aba-4309-9060-5077577af5d8' User entered '12 Jan 2021 17:59:40'	System	12 Jan 2021 22:59:50
	System	12 Jan 2021 22:59:50

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 13:32:40

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

[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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-01-18T12:15:35', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'a192b2f7-cca2-4a4f-87d9-5ba9e0e29b4c' User entered 'No (N)'	System	18 Jan 2021 17:15:49
	System	18 Jan 2021 17:15:49



US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

Have you been exposed to someone with 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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-01-18T12:15:41', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'a192b2f7-cca2-4a4f-87d9-5ba9e0e29b4c'	System	18 Jan 2021 17:15:49
User entered 'No (N)'	System	18 Jan 2021 17:15:49

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-01-18T12:15:44', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'a192b2f7-cca2-4a4f-87d9-5ba9e0e29b4c' User entered '18 Jan 2021 12:15:44'	System	18 Jan 2021 17:15:49
	System	18 Jan 2021 17:15:49

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-01-23T13:10:22', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '4d117464-f2dc-4959-a564-f0bd6e309dc6' User entered 'No (N)'	System	27 Jan 2021 01:07:17
	System	27 Jan 2021 01:07:17

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

Have you been exposed to someone with 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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-01-23T13:10:25', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '4d117464-f2dc-4959-a564-f0bd6e309dc6' User entered 'No (N)'	System	27 Jan 2021 01:07:17

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-01-23T13:10:28', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '4d117464-f2dc-4959-a564-f0bd6e309dc6' User entered '23 Jan 2021 13:10:28'	System	27 Jan 2021 01:07:17
	System	27 Jan 2021 01:07:17



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-02-02T17:59:13', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '4f21e78c-d614-43f2-a617-bbbdbf72762c' User entered 'No (N)'	System	03 Feb 2021 04:58:53
	System	03 Feb 2021 04:58:53

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

Have you been exposed to someone with 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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-02-02T17:59:17', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '4f21e78c-d614-43f2-a617-bbbdbf72762c' User entered 'No (N)'	System	03 Feb 2021 04:58:53

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-02-02T17:59:20', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '4f21e78c-d614-43f2-a617-bbbdbf72762c' User entered '02 Feb 2021 17:59:20'	System	03 Feb 2021 04:58:53
	System	03 Feb 2021 04:58:53

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 13:32:40



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-02-07T18:10:47', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '9501bb7d-6245-4bdb-b306-8ec22f127d26' User entered 'No (N)'	System	07 Feb 2021 23:12:17
	System	07 Feb 2021 23:12:17

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

Have you been exposed to someone with 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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-02-07T18:10:50', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '9501bb7d-6245-4bdb-b306-8ec22f127d26'	System	07 Feb 2021 23:12:17
User entered 'No (N)'	System	07 Feb 2021 23:12:17

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-02-07T18:10:53', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '9501bb7d-6245-4bdb-b306-8ec22f127d26'	System	07 Feb 2021 23:12:17
User entered '07 Feb 2021 18:10:53'	System	07 Feb 2021 23:12:17

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-02-13T08:15:01', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '035ce2bf-8ac4-47da-9180-7311c364761c' User entered 'No (N)'	System	13 Feb 2021 13:15:11
	System	13 Feb 2021 13:15:11



US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

Have you been exposed to someone with 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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-02-13T08:15:02', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '035ce2bf-8ac4-47da-9180-7311c364761c' User entered 'No (N)'	System	13 Feb 2021 13:15:11

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-02-13T08:15:06', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '035ce2bf-8ac4-47da-9180-7311c364761c' User entered '13 Feb 2021 08:15:06'	System	13 Feb 2021 13:15:11
	System	13 Feb 2021 13:15:11

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-02-20T14:56:04', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '2fccf5be-7a20-48b4-a3ed-d07e07c941bf' User entered 'No (N)'	System	20 Feb 2021 19:56:12
	System	20 Feb 2021 19:56:12

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

Have you been exposed to someone with 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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-02-20T14:56:06', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '2fccf5be-7a20-48b4-a3ed-d07e07c941bf' User entered 'No (N)'	System	20 Feb 2021 19:56:12

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-02-20T14:56:09', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '2fccf5be-7a20-48b4-a3ed-d07e07c941bf' User entered '20 Feb 2021 14:56:09'	System	20 Feb 2021 19:56:12



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-02-27T00:03:26', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '34f4b30d-81a3-4775-9bf1-f7575c23583e' User entered 'No (N)'	System	27 Feb 2021 05:06:31

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

Have you been exposed to someone with 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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-02-27T00:03:30', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '34f4b30d-81a3-4775-9bf1-f7575c23583e' User entered 'No (N)'	System	27 Feb 2021 05:06:31

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-02-27T00:03:32', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '34f4b30d-81a3-4775-9bf1-f7575c23583e' User entered '27 Feb 2021 00:03:32'	System	27 Feb 2021 05:06:31
	System	27 Feb 2021 05:06:31

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 13:32:40



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-03-06T20:16:49', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'd75a4438-8e04-4cad-8364-eeb256375db3'	System	07 Mar 2021 01:17:00
User entered 'No (N)'	System	07 Mar 2021 01:17:00

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

Have you been exposed to someone with 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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-03-06T20:16:52', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'd75a4438-8e04-4cad-8364-eeb256375db3'	System	07 Mar 2021 01:17:00
User entered 'No (N)'	System	07 Mar 2021 01:17:00

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-03-06T20:16:55', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'd75a4438-8e04-4cad-8364-eeb256375db3' User entered '06 Mar 2021 20:16:55'	System	07 Mar 2021 01:17:00
	System	07 Mar 2021 01:17:00

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-03-13T08:00:47', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '7ff16da8-7269-4192-92c7-b3c4bd95aca8'	System	13 Mar 2021 13:00:54
User entered 'No (N)'	System	13 Mar 2021 13:00:54



US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

Have you been exposed to someone with 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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-03-13T08:00:49', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '7ff16da8-7269-4192-92c7-b3c4bd95aca8'	System	13 Mar 2021 13:00:54
User entered 'No (N)'	System	13 Mar 2021 13:00:54

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-03-13T08:00:52', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '7ff16da8-7269-4192-92c7-b3c4bd95aca8' User entered '13 Mar 2021 08:00:52'	System	13 Mar 2021 13:00:54
	System	13 Mar 2021 13:00:54

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-03-20T09:18:10', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '6259287c-3cf3-4db7-95a8-71f4209ab532'	System	20 Mar 2021 13:18:18
User entered 'No (N)'	System	20 Mar 2021 13:18:18

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

Have you been exposed to someone with 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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-03-20T09:18:13', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '6259287c-3cf3-4db7-95a8-71f4209ab532'	System	20 Mar 2021 13:18:18
User entered 'No (N)'	System	20 Mar 2021 13:18:18

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-03-20T09:18:15', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '6259287c-3cf3-4db7-95a8-71f4209ab532' User entered '20 Mar 2021 09:18:15'	System	20 Mar 2021 13:18:18
	System	20 Mar 2021 13:18:18



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-03-27T09:33:48', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '7c597da2-c1f8-49d9-beba-c676ae90bdcd' User entered 'No (N)'	System	27 Mar 2021 13:34:05

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

Have you been exposed to someone with 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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-03-27T09:33:56', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '7c597da2-c1f8-49d9-beba-c676ae90bdcd' User entered 'No (N)'	System	27 Mar 2021 13:34:05

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-03-27T09:34:01', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '7c597da2-c1f8-49d9-beba-c676ae90bdcd' User entered '27 Mar 2021 09:34:01'	System	27 Mar 2021 13:34:05
	System	27 Mar 2021 13:34:05

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 13:32:40



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-04-03T16:45:26', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'f5d58847-1122-4794-b20b-429717802740'	System	03 Apr 2021 20:45:38
User entered 'No (N)'	System	03 Apr 2021 20:45:38

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

Have you been exposed to someone with 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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-04-03T16:45:28', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'f5d58847-1122-4794-b20b-429717802740'	System	03 Apr 2021 20:45:38
User entered 'No (N)'	System	03 Apr 2021 20:45:38

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-04-03T16:45:32', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'f5d58847-1122-4794-b20b-429717802740'	System	03 Apr 2021 20:45:38
User entered '03 Apr 2021 16:45:32'	System	03 Apr 2021 20:45:38

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 13:32:40

US3432641

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-04-10T07:53:38', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '8578b746-b11e-40c6-a382-6a67571ca4c7' User entered 'No (N)'	System	10 Apr 2021 11:53:53
	System	10 Apr 2021 11:53:53



US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

Have you been exposed to someone with 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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-04-10T07:53:40', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '8578b746-b11e-40c6-a382-6a67571ca4c7' User entered 'No (N)'	System	10 Apr 2021 11:53:53

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-04-10T07:53:45', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '8578b746-b11e-40c6-a382-6a67571ca4c7' User entered '10 Apr 2021 07:53:45'	System	10 Apr 2021 11:53:53
	System	10 Apr 2021 11:53:53

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-04-17T16:09:13', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'a57d151a-e19b-41f4-8ad5-f7b3f105a7dd' User entered 'No (N)'	System	17 Apr 2021 20:09:23
	System	17 Apr 2021 20:09:23

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Have you been exposed to someone with 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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-04-17T16:09:17', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'a57d151a-e19b-41f4-8ad5-f7b3f105a7dd' User entered 'No (N)'	System	17 Apr 2021 20:09:23

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-04-17T16:09:19', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: 'a57d151a-e19b-41f4-8ad5-f7b3f105a7dd' User entered '17 Apr 2021 16:09:19'	System	17 Apr 2021 20:09:23
	System	17 Apr 2021 20:09:23



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-04-24T08:39:10', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '36934f36-add3-41ca-beac-43d81c9d67d2' User entered 'No (N)'	System	24 Apr 2021 12:39:21
	System	24 Apr 2021 12:39:21

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

Have you been exposed to someone with 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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-04-24T08:39:15', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '36934f36-add3-41ca-beac-43d81c9d67d2' User entered 'No (N)'	System	24 Apr 2021 12:39:21

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-04-24T08:39:17', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '36934f36-add3-41ca-beac-43d81c9d67d2' User entered '24 Apr 2021 08:39:17'	System	24 Apr 2021 12:39:21
	System	24 Apr 2021 12:39:21

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 13:32:40



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-05-01T20:47:13', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '958bd0ac-2cc0-4203-8db2-f2c123e9cb05' User entered 'Yes (Y)'	System	02 May 2021 00:48:13
	System	02 May 2021 00:48:13

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

Have you been exposed to someone with 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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-05-01T20:47:19', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '958bd0ac-2cc0-4203-8db2-f2c123e9cb05' User entered 'Yes (Y)'	System	02 May 2021 00:48:13
	System	02 May 2021 00:48:13

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Please 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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-05-01T20:47:26', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '958bd0ac-2cc0-4203-8db2-f2c123e9cb05'	System	02 May 2021 00:48:13
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 May 2021 00:48:13

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-05-01T20:47:34', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '958bd0ac-2cc0-4203-8db2-f2c123e9cb05'	System	02 May 2021 00:48:13
User entered 'No (N)'	System	02 May 2021 00:48:13

US3432641

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:40:32

[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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-05-01T20:47:48', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '958bd0ac-2cc0-4203-8db2-f2c123e9cb05' User entered 'Yes (Y)'	System	02 May 2021 00:48:13
	System	02 May 2021 00:48:13

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Please 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 (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-05-01T20:47:52', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '958bd0ac-2cc0-4203-8db2-f2c123e9cb05'	System	02 May 2021 00:48:13
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 May 2021 00:48:13

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-05-01T20:47:56', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '958bd0ac-2cc0-4203-8db2-f2c123e9cb05'	System	02 May 2021 00:48:13
User entered '01 May 2021 20:47:56'	System	02 May 2021 00:48:13



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 13:32:40



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 13:32:40



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 13:32:40



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 13:32:40



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 13:32:40



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 13:32:40



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 13:32:40



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 13:32:40



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 13:32:40



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 13:32:40



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 13:32:40



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 13:32:40



**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 13:32:40



**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 13:32:40



**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 13:32:40



**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 13:32:40



**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 13:32:40



**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 13:32:40



**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 13:32:40



**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 13:32:40



**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 13:32:40



**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 13:32:40



**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 13:32:40



**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 13:32:40



**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 13:32:40



**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 13:32:40



**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 13:32:40



**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 13:32:40



**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 13:32:40



**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 13:32:40



**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '19 Nov 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '23 Nov 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '26 Nov 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '30 Nov 2022 23:59'	System	20 Nov 2020 13:32:40



**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '03 Dec 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '07 Dec 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '10 Dec 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '14 Dec 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '17 Dec 2022 00:01'	System	20 Nov 2020 13:32:40



**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '21 Dec 2022 23:59'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '24 Dec 2022 00:01'	System	20 Nov 2020 13:32:40

**US3432641**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:40:32**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:32:40
Amendment Manager: User entered '28 Dec 2022 23:59'	System	20 Nov 2020 13:32:40

US3432641

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:40:32**

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 06:25:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-03-02T12:26:31', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '7de8f65f-3b90-4d5b-b58f-a76039b3674e'	System	02 Mar 2021 17:26:40
User entered 'No (N)'	System	02 Mar 2021 17:26:40

**US3432641**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:40:32**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:25:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5670F7B4-1062-46C1-9750-D3AA1EEB56D6)', Time: '2021-03-02T12:26:34', User OID: 'PatientReportedOutcome (US3432641)', ODM File OID: '7de8f65f-3b90-4d5b-b58f-a76039b3674e' User entered '02 Mar 2021 12:26:34'	System	02 Mar 2021 17:26:40
	System	02 Mar 2021 17:26:40

**US3432641**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:40:32**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 16:11:54

**US3432641**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:40:32**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '20 Jan 2021'	(b) (4), (b) (6)	20 Jan 2021 16:11:54



US3432641

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Jan 2021 16:11:54

US3432641

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:32

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered empty.	(b) (4), (b) (6)	20 Jan 2021 16:11:54

US3432641

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Jan 2021 16:11:59

**US3432641**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:40:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:09:15
User entered 'l'	System	20 Jan 2021 16:11:59

**US3432641**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:40:32**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:53:38
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 17:27:02

US3432641

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:32

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:53:38
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered '22 Feb 2021'	(b) (4), (b) (6)	22 Mar 2021 17:27:02

**US3432641**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:40:32**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:53:38
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	22 Mar 2021 17:27:02

US3432641

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:32

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:53:38
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'Called pt on 2/24 @ 16:36, and 2/25 @ 12:31 . Pt was not reached'	(b) (4), (b) (6)	22 Mar 2021 17:27:02



US3432641

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:53:38
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Mar 2021 17:27:07

**US3432641**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:40:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:53:38
User entered 'l'	System	22 Mar 2021 17:27:07

US3432641

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	21 Apr 2021 13:11:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Tenaizus Woods (b) (4)	21 Apr 2021 13:11:10
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	21 Apr 2021 13:11:02
User entered 'No (N)'	Tenaizus Woods (b) (4)	21 Apr 2021 13:11:02

US3432641

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:32

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User entered '25 Mar 2021'	Tenaizus Woods (b) (4)	21 Apr 2021 13:11:02
	(b) (4)	

US3432641

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User entered 'Contact Not Made (CONTACT NOT MADE)'	Tenaizus Woods (b) (4)	21 Apr 2021 13:11:02

US3432641

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:32

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User entered 'Contacted 22MAR2021, No answer. LVM Contacted 25MAR2021, No answer. LVM.'	Tenaizus Woods (b) (4) (b) (4)	21 Apr 2021 13:11:02

US3432641

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User entered 'Yes (Y)'	Tenaizus Woods (b) (4)	21 Apr 2021 13:11:13
	(b) (4)	

**US3432641**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:40:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Apr 2021 13:11:13



US3432641

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User entered 'Yes (Y)'	Tenaizus Woods (b) (4)	21 Apr 2021 13:12:52
	(b) (4)	

US3432641

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:32

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User entered '21 Apr 2021'	Tenaizus Woods (b) (4)	21 Apr 2021 13:12:52
	(b) (4)	

US3432641

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:32

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User entered 'Contact Made (CONTACT MADE)'	Tenaizus Woods (b) (4)	21 Apr 2021 13:12:52
	(b) (4)	

US3432641

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:40:32

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User entered empty.	Tenaizus Woods (b) (4)	21 Apr 2021 13:12:52
	(b) (4)	

US3432641

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:40:32

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User entered 'Yes (Y)'	Tenaizus Woods (b) (4)	21 Apr 2021 13:13:00
	(b) (4)	

**US3432641**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:40:32**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Apr 2021 13:13:00

US3432641

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	Austin Kim (b) (4) (b) (4)	08 Jan 2021 17:47:14

US3432641

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:32

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '08 Jan 2021'	Austin Kim (b) (4) (b) (4)	08 Jan 2021 17:47:14



US3432641

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:32

[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 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Clinic (Clinic)'	Austin Kim (b) (4) (b) (4)	08 Jan 2021 17:47:14

US3432641

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:40:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User entered 'UNBLND_DECIDE'	System	08 Jan 2021 17:47:14

US3432641

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:40:32

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '08 Jan 2021'	Austin Kim (b) (4) (b) (4)	08 Jan 2021 17:47:32

US3432641

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:40:32

[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 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered '0'	Jun Bai Park Chang	31 Mar 2021 16:28:53
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 09:58:25

US3432641

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:40:32

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	Austin Kim (b) (4) (b) (4)	08 Jan 2021 17:47:32

US3432641

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:40:32

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'Amendment 6 or later (Amendment 6 or later)'	Jun Bai Park Chang (b) (4)	31 Mar 2021 16:28:53
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:58:25

US3432641

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:40:32

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '08 Jan 2021'	Austin Kim (b) (4) (b) (4)	08 Jan 2021 17:47:32

US3432641

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:40:32

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'mRNA-1273 (mRNA-1273)'	Austin Kim (b) (4) (b) (4)	08 Jan 2021 17:47:32



US3432641

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:40:32

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 05:20:50
User entered 'mRNA-1273 (mRNA-1273)'	Austin Kim (b) (4)	08 Jan 2021 17:47:32

US3432641

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:40:32

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 05:20:50
User entered 'mRNA-1273 (mRNA-1273)'	Austin Kim (b) (4)	08 Jan 2021 17:47:32

US3432641

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:40:32

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'No (N)'	Austin Kim (b) (4) (b) (4)	08 Jan 2021 17:47:32

US3432641

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:40:32

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User entered empty.	System	08 Jan 2021 17:47:32

**US3432641**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:40:32**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User entered empty.	System	08 Jan 2021 17:47:32

US3432641

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	Austin Kim (b) (4) (b) (4)	08 Jan 2021 17:47:44

US3432641

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:32

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 08Jan2021 is recorded under the OL-1 visit in EDC, however the same is reported under Visit 3 Day 57 visit in PPD Central lab. Please reconcile and confirm the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 08Jan2021 is recorded under the OL-1 visit in EDC, however the same is reported under Visit 3 Day 57 visit in PPD Central lab. Please reconcile and confirm the correct Visit and update if applicable. Else clarify, thank you.' answered with 'Participant had a combined visit OL-1 and v3, this is why the lab req is the same.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 13:41:00
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 08Jan2021 is recorded under the OL-1 visit in EDC, however the same is reported under Visit 3 Day 57 visit in PPD Central lab. Please reconcile and confirm the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	Austin Kim (b) (4) (b) (4)	24 Feb 2021 21:34:42
User signature succeeded.	(b) (4), (b) (6)	24 Feb 2021 16:17:39
User entered '08 Jan 2021'	Lindsey Baden (b) (4) Austin Kim (b) (4) (b) (4)	19 Feb 2021 03:38:20 08 Jan 2021 17:47:44

US3432641

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:32

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '11:00'	Austin Kim (b) (4) (b) (4)	08 Jan 2021 17:47:44



US3432641

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:40:32

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User entered '08 Jan 2021 11:00'	System	08 Jan 2021 17:47:44

US3432641

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:40:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	Austin Kim (b) (4) (b) (4)	08 Jan 2021 17:47:54

US3432641

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:40:32

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '08 Jan 2021'	Austin Kim (b) (4) (b) (4)	08 Jan 2021 17:47:54

**US3432641**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:40:32**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered '11:10'	Austin Kim (b) (4) (b) (4)	08 Jan 2021 17:47:54

**US3432641**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:40:32**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:11:18
User entered '08 Jan 2021 11:10'	System	08 Jan 2021 17:47:54

US3432641

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:40:32

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:31:17
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	10 Dec 2020 18:12:55

US3432641

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:32

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Dyspepsia - version MedDRA\\23.0.	Coder Import (b) (4)	10 Dec 2020 18:15:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Dec 2020 18:15:06
Data point term sent to Coder	System	10 Dec 2020 18:13:57
User entered 'dyspepsia'	Phoebe Cunningham (b) (4)	10 Dec 2020 18:13:52

US3432641

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User entered 'No (N)'	Phoebe Cunningham (b) (4)	10 Dec 2020 18:13:52



US3432641

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User entered 'No (N)'	Phoebe Cunningham (b) (4)	10 Dec 2020 18:13:52

US3432641

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User entered 'No (N)'	Phoebe Cunningham (b) (4)	10 Dec 2020 18:13:52

US3432641

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User entered '25 Nov 2020'	Phoebe Cunningham (b) (4)	10 Dec 2020 18:13:52

US3432641

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:32

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User closed query 'Per CDM: Previous response states start date imore than 24 hours after dose, however Start Date 25Nov2020 is the same day as Visit 2 dose date were the Exposure page. Please review and update as appropriate.' (Site from DM). Query 'Per CDM: Previous response states start date imore than 24 hours after dose, however Start Date 25Nov2020 is the same day as Visit 2 dose date were the Exposure page. Please review and update as appropriate.' answered with 'per participant's reponse, the time is unknown when reported' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 13:43:01
User opened query 'Per CDM: Previous response states start date imore than 24 hours after dose, however Start Date 25Nov2020 is the same day as Visit 2 dose date were the Exposure page. Please review and update as appropriate.' answered with 'per participant's reponse, the time is unknown when reported' (Site from DM).	Natalie Izaguirre (b) (4)	07 Apr 2021 21:55:07
User opened query 'Per CDM: Previous response states start date imore than 24 hours after dose, however Start Date 25Nov2020 is the same day as Visit 2 dose date were the Exposure page. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 16:36:48
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	21 Jan 2021 16:34:32
Query 'Data is required. Please provide.' answered with 'data field is not required, start date more than 24 hours after dose' (Site from System).	Megan Powell (b) (4)	15 Jan 2021 14:08:32
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Dec 2020 18:13:52
User entered empty.	Phoebe Cunningham (b) (4)	10 Dec 2020 18:13:52

US3432641

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Dec 2020 18:13:52

US3432641

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User entered 'No (N)'	Phoebe Cunningham (b) (4)	10 Dec 2020 18:13:52

US3432641

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User entered '27 Nov 2020'	Phoebe Cunningham (b) (4)	10 Dec 2020 18:13:52

US3432641

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:32

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	11 Dec 2020 05:14:04
Query 'Data is required. Please provide.' answered with 'greater than 24 hours from injection' (Site from System).	Phoebe Cunningham (b) (4)	10 Dec 2020 18:15:02
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Dec 2020 18:13:52
User entered empty.	Phoebe Cunningham (b) (4)	10 Dec 2020 18:13:52



**US3432641**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:40:32**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Dec 2020 18:13:52

US3432641

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:32

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User entered 'Grade 1/Mild (Grade 1/Mild)'	Phoebe Cunningham (b) (4)	10 Dec 2020 18:13:52

US3432641

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User entered 'No (N)'	Phoebe Cunningham (b) (4)	10 Dec 2020 18:13:52

US3432641

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:32

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User entered '0'	Phoebe Cunningham (b) (4)	10 Dec 2020 18:13:52

US3432641

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User entered '0'	Phoebe Cunningham (b) (4)	10 Dec 2020 18:13:52

US3432641

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User entered '0'	Phoebe Cunningham (b) (4)	10 Dec 2020 18:13:52

US3432641

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User entered empty.	Phoebe Cunningham (b) (4)	10 Dec 2020 18:13:52

US3432641

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:32

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User entered empty.	Phoebe Cunningham (b) (4)	10 Dec 2020 18:13:52



US3432641

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User entered empty.	Phoebe Cunningham (b) (4)	10 Dec 2020 18:13:52

US3432641

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User entered empty.	Phoebe Cunningham (b) (4)	10 Dec 2020 18:13:52

US3432641

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User entered '0'	Phoebe Cunningham (b) (4)	10 Dec 2020 18:13:52

US3432641

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User entered '0'	Phoebe Cunningham (b) (4)	10 Dec 2020 18:13:52

US3432641

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User entered '0'	Phoebe Cunningham (b) (4)	10 Dec 2020 18:13:52

US3432641

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User entered 'Not Related (NOT RELATED)'	Phoebe Cunningham (b) (4)	10 Dec 2020 18:13:52

US3432641

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User entered 'Not Related (NOT RELATED)'	Phoebe Cunningham (b) (4)	10 Dec 2020 18:13:52

US3432641

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User entered 'Not Applicable (NOT APPLICABLE)'	Phoebe Cunningham (b) (4)	10 Dec 2020 18:13:52



US3432641

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:32

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User entered '0'	Phoebe Cunningham (b) (4)	10 Dec 2020 18:13:52

US3432641

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User entered 'I'	Phoebe Cunningham (b) (4)	10 Dec 2020 18:13:52

US3432641

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User entered '0'	Phoebe Cunningham (b) (4)	10 Dec 2020 18:13:52

US3432641

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:32

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Phoebe Cunningham (b) (4)	10 Dec 2020 18:13:52

US3432641

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:32

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User entered empty.	Phoebe Cunningham (b) (4)	10 Dec 2020 18:13:52

US3432641

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:32

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:31:28
User entered empty.	Phoebe Cunningham (b) (4)	10 Dec 2020 18:13:52

US3432641

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:40:32

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	10 Dec 2020 18:13:52

**US3432641**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:40:32**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Dec 2020 18:13:52



US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 11 Aug 2021 22:40:32**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:31:17
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:38:20
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	23 Oct 2020 11:31:20

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:40:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 11:34:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 11:34:29
Data point term sent to Coder	System	23 Oct 2020 11:33:30
User entered 'claritin'	Bruce Bausk (b) (4)	23 Oct 2020 11:32:53

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:40:32**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'No (N)'	Bruce Bausk (b) (4)	23 Oct 2020 11:32:53
	(b) (4)	

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:40:32**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'seasonal allergies'	Bruce Bausk (b) (4)	23 Oct 2020 11:32:53
	(b) (4)	

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:40:32**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered '10'	Bruce Bausk (b) (4)	23 Oct 2020 11:32:53

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:40:32**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'mg (mg)'	Bruce Bausk (b) (4)	23 Oct 2020 11:32:53
	(b) (4)	

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:40:32**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered empty.	Bruce Bausk (b) (4)	23 Oct 2020 11:32:53
	(b) (4)	

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:40:32**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'as needed (PRN)'	Bruce Bausk (b) (4)	23 Oct 2020 11:32:53
	(b) (4)	



US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:40:32**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered empty.	Bruce Bausk (b) (4)	23 Oct 2020 11:32:53
	(b) (4)	

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:40:32**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'Oral (ORAL)'	Bruce Bausk (b) (4)	23 Oct 2020 11:32:53
	(b) (4)	

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:40:32**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered empty.	Bruce Bausk (b) (4)	23 Oct 2020 11:32:53
	(b) (4)	

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:40:32

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'un UNK 2015'	Bruce Bausk (b) (4)	23 Oct 2020 11:32:53
	(b) (4)	

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:40:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered '0'	Bruce Bausk (b) (4)	23 Oct 2020 11:32:53
	(b) (4)	

**US3432641**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:40:32**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	23 Oct 2020 11:32:53
	(b) (4)	

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:40:32**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered empty.	Bruce Bausk (b) (4)	23 Oct 2020 11:32:53
	(b) (4)	

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:40:32**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'No (N)'	Bruce Bausk (b) (4)	23 Oct 2020 11:32:53
	(b) (4)	



US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:40:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 11:32:53

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:40:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 11:32:53

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:40:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 11:32:53

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:40:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
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)	23 Oct 2020 11:35:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 11:35:33
Data point term sent to Coder	System	23 Oct 2020 11:34:31
User entered 'albuterol'	Bruce Bausk (b) (4)	23 Oct 2020 11:34:10

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:40:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'No (N)'	Bruce Bausk (b) (4)	23 Oct 2020 11:34:10
	(b) (4)	

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:40:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'seasonal allergies'	Bruce Bausk (b) (4)	23 Oct 2020 11:34:10
	(b) (4)	

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:40:32**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'I'	Bruce Bausk (b) (4)	23 Oct 2020 11:34:10
	(b) (4)	

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:40:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'puff (PUFF)'	Bruce Bausk (b) (4)	23 Oct 2020 11:34:10
	(b) (4)	



US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:40:32**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered empty.	Bruce Bausk (b) (4)	23 Oct 2020 11:34:10
	(b) (4)	

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:40:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'as needed (PRN)'	Bruce Bausk (b) (4)	23 Oct 2020 11:34:10
	(b) (4)	

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:40:32**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered empty.	Bruce Bausk (b) (4)	23 Oct 2020 11:34:10
	(b) (4)	

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:40:32**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Bruce Bausk (b) (4)	23 Oct 2020 11:34:10

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:40:32**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered empty.	Bruce Bausk (b) (4)	23 Oct 2020 11:34:10
	(b) (4)	

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:40:32**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'un UNK 2015'	Bruce Bausk (b) (4)	23 Oct 2020 11:34:10
	(b) (4)	

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:40:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered '0'	Bruce Bausk (b) (4)	23 Oct 2020 11:34:10
	(b) (4)	

**US3432641**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:40:32**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	23 Oct 2020 11:34:10
	(b) (4)	



US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:40:32**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered empty.	Bruce Bausk (b) (4)	23 Oct 2020 11:34:10
	(b) (4)	

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:40:32**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'No (N)'	Bruce Bausk (b) (4)	23 Oct 2020 11:34:10

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:40:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 11:34:10

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:40:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 11:34:10

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:40:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 11:34:10

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:40:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 11:36:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Oct 2020 11:36:33
Data point term sent to Coder	System	23 Oct 2020 11:35:34
User entered 'aleve'	Bruce Bausk (b) (4)	23 Oct 2020 11:34:45

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:40:32**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'No (N)'	Bruce Bausk (b) (4)	23 Oct 2020 11:34:45
	(b) (4)	

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:40:32**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'headache'	Bruce Bausk (b) (4)	23 Oct 2020 11:34:45
	(b) (4)	



US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:40:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'l'	Bruce Bausk (b) (4)	23 Oct 2020 11:34:45

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:40:32**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'tablet (TABLET)'	Bruce Bausk (b) (4)	23 Oct 2020 11:34:45
	(b) (4)	

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:40:32**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered empty.	Bruce Bausk (b) (4)	23 Oct 2020 11:34:45
	(b) (4)	

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:40:32**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'as needed (PRN)'	Bruce Bausk (b) (4)	23 Oct 2020 11:34:45
	(b) (4)	

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:40:32**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered empty.	Bruce Bausk (b) (4)	23 Oct 2020 11:34:45
	(b) (4)	

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:40:32**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'Oral (ORAL)'	Bruce Bausk (b) (4)	23 Oct 2020 11:34:45
	(b) (4)	

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:40:32**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered empty.	Bruce Bausk (b) (4)	23 Oct 2020 11:34:45
	(b) (4)	

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:40:32

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'un UNK 2000'	Bruce Bausk (b) (4)	23 Oct 2020 11:34:45
	(b) (4)	



US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:40:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered '0'	Bruce Bausk (b) (4)	23 Oct 2020 11:34:45
	(b) (4)	

**US3432641**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:40:32**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	23 Oct 2020 11:34:45
	(b) (4)	

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:40:32**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered empty.	Bruce Bausk (b) (4)	23 Oct 2020 11:34:45
	(b) (4)	

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:40:32**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'No (N)'	Bruce Bausk (b) (4)	23 Oct 2020 11:34:45
	(b) (4)	

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:40:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 11:34:45

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:40:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 11:34:45

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:40:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 11:34:45

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:40:32

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;NORETHISTERONE ACETATE, PRODUCTSYNONYM: AUROVELA 1/20 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Apr 2021 19:01:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Apr 2021 19:01:38
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;FERROUS FUMARATE;NORETHISTERONE ACETATE, PRODUCTSYNONYM: AUROVELA 24 FE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 12:27:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 12:27:29
Data point term sent to Coder	System	23 Oct 2020 11:35:34
User entered 'aurovela'	Bruce Bausk (b) (4)	23 Oct 2020 11:35:14



US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:40:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 07:12:06
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'Per query instruction, updated to prophylaxis' (Site from DM).	Megan Powell (b) (4) (b) (4)	14 Jan 2021 23:19:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Megan Powell (b) (4) (b) (4)	14 Jan 2021 23:18:50
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 05:28:06
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	23 Oct 2020 11:35:14

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:40:32**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'birth control'	Bruce Bausk (b) (4)	23 Oct 2020 11:35:14
	(b) (4)	

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:40:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User closed query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of tablets (e.g., Dose = 1/20 or 1.5/30 ; Unit = MG/MCG). Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 07:12:09
Query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of tablets (e.g., Dose = 1/20 or 1.5/30 ; Unit = MG/MCG). Please update as appropriate.' answered with 'dosage unknown. subject reported taking 1 tablet' (Site from DM).	Megan Powell (b) (4) (b) (4)	14 Jan 2021 23:18:23
User opened query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of tablets (e.g., Dose = 1/20 or 1.5/30 ; Unit = MG/MCG). Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 05:28:17
User entered 'I'	Bruce Bausk (b) (4) (b) (4)	23 Oct 2020 11:35:14

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:40:32**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'tablet (TABLET)'	Bruce Bausk (b) (4)	23 Oct 2020 11:35:14
	(b) (4)	

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:40:32**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered empty.	Bruce Bausk (b) (4)	23 Oct 2020 11:35:14
	(b) (4)	

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:40:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'once daily (QD)'	Bruce Bausk (b) (4)	23 Oct 2020 11:35:14
	(b) (4)	

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:40:32**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered empty.	Bruce Bausk (b) (4)	23 Oct 2020 11:35:14
	(b) (4)	

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:40:32**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'Oral (ORAL)'	Bruce Bausk (b) (4)	23 Oct 2020 11:35:14
	(b) (4)	



US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:40:32**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered empty.	Bruce Bausk (b) (4)	23 Oct 2020 11:35:14
	(b) (4)	

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:40:32**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'un Apr 2020'	Bruce Bausk (b) (4)	23 Oct 2020 11:35:14
	(b) (4)	

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:40:32**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered '0'	Bruce Bausk (b) (4)	23 Oct 2020 11:35:14
	(b) (4)	

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:40:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	23 Oct 2020 11:35:14
	(b) (4)	

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:40:32**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered empty.	Bruce Bausk (b) (4)	23 Oct 2020 11:35:14
	(b) (4)	

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:40:32**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'No (N)'	Bruce Bausk (b) (4)	23 Oct 2020 11:35:14
	(b) (4)	

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:40:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	23 Oct 2020 11:35:14

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:40:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Oct 2020 11:35:14



US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:40:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 11:35:14

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:40:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:45
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 19:12:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 19:12:57
Data point term sent to Coder	System	30 Oct 2020 19:12:50
User entered 'Motrin'	(b) (4), (b) (6)	30 Oct 2020 19:11:54

**US3432641**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:40:32**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:45
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'No (N)'	(b) (4), (b) (6)	30 Oct 2020 19:11:54

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:40:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:45
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User closed query 'Per CDM re-query: Please confirm in query response, the solicited event doesn't meet any of the AE reporting criteria mentioned per previous query else add AE as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 12:28:50
Query 'Per CDM re-query: Please confirm in query response, the solicited event doesn't meet any of the AE reporting criteria mentioned per previous query else add AE as appropriate. ' answered with 'solicited event doesn't meet ae reporting criteria' (Site from DM).	Austin Kim (b) (4) (b) (4)	24 Feb 2021 21:33:21
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. 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 of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 09:46:16
User opened query 'Per CDM re-query: Please confirm in query response, the solicited event doesn't meet any of the AE reporting criteria mentioned per previous query else add AE as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 09:46:15

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:40:32

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. 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 of 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 'see diary' (Site from DM).	Monica Feeley (b) (4) (b) (4)	25 Jan 2021 18:45:00
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. 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 of 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)	14 Jan 2021 05:28:41
User entered 'Headache'	(b) (4), (b) (6)	30 Oct 2020 19:11:54

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:40:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:45
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered '500'	(b) (4), (b) (6)	30 Oct 2020 19:11:54

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:40:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:45
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'mg (mg)'	(b) (4), (b) (6)	30 Oct 2020 19:11:54

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:40:32**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:45
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 19:11:54



US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:40:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:45
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'once (ONCE)'	(b) (4), (b) (6)	30 Oct 2020 19:11:54

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:40:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:45
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 19:11:54

**US3432641**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:40:32**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:45
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	30 Oct 2020 19:11:54

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:40:32**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:45
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered empty.	(b) (4), (b) (6)	30 Oct 2020 19:11:54

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:40:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:45
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered '26 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 19:11:54

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:40:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:45
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered '0'	(b) (4), (b) (6)	30 Oct 2020 19:11:54

**US3432641**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:40:32**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:45
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'No (N)'	(b) (4), (b) (6)	30 Oct 2020 19:11:54

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:40:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:45
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered '26 Oct 2020'	(b) (4), (b) (6)	30 Oct 2020 19:11:54



US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:40:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:45
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Oct 2020 19:11:54

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:40:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:45
User entered empty.	System	30 Oct 2020 19:11:54

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:40:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:45
User entered empty.	System	30 Oct 2020 19:11:54

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:40:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:45
User entered empty.	System	30 Oct 2020 19:11:54

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:40:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:41
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
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 21:14:46
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 21:14:46
Data point term sent to Coder	System	02 Dec 2020 21:14:14
User entered 'TYLENOL'	Kathleen Garvey (b) (4)	02 Dec 2020 21:14:07

**US3432641**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:40:32**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:41
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'No (N)'	Kathleen Garvey (b) (4)	02 Dec 2020 21:14:07

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:40:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:41
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
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 INJECTION SITE PAIN AND MUSCLE ACHES 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 INJECTION SITE PAIN AND MUSCLE ACHES did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 08:22:32
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN AND MUSCLE ACHES 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 INJECTION SITE PAIN AND MUSCLE ACHES did not meet the AE reporting criteria.' answered with 'no AE needed' (Site from DM).	Monica Feeley (b) (4)	04 Feb 2021 22:46:23

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:40:32

[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 INJECTION SITE PAIN AND MUSCLE ACHES 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 INJECTION SITE PAIN AND MUSCLE ACHES did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 06:48:09
User entered 'INJECTION SITE PAIN AND MUSCLE ACHES'	Kathleen Garvey (b) (4) (b) (4)	02 Dec 2020 21:14:07



US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:40:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:41
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered '500'	Kathleen Garvey (b) (4)	02 Dec 2020 21:14:07

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:40:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:41
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'mg (mg)'	Kathleen Garvey (b) (4)	02 Dec 2020 21:14:07

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:40:32**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:41
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered empty.	Kathleen Garvey (b) (4)	02 Dec 2020 21:14:07

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:40:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:41
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'twice daily (BID)'	Kathleen Garvey (b) (4)	02 Dec 2020 21:14:07

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:40:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:41
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered empty.	Kathleen Garvey (b) (4)	02 Dec 2020 21:14:07

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:40:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:41
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'Oral (ORAL)'	Kathleen Garvey (b) (4)	02 Dec 2020 21:14:07

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:40:32**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:41
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered empty.	Kathleen Garvey (b) (4)	02 Dec 2020 21:14:07

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:40:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:41
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered '25 Nov 2020'	Kathleen Garvey (b) (4)	02 Dec 2020 21:14:07



US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:40:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:41
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered '0'	Kathleen Garvey (b) (4)	02 Dec 2020 21:14:07

**US3432641**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:40:32**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:41
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'No (N)'	Kathleen Garvey (b) (4)	02 Dec 2020 21:14:07

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:40:32**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:41
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered '26 Nov 2020'	Kathleen Garvey (b) (4)	02 Dec 2020 21:14:07

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:40:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:41
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	02 Dec 2020 21:14:07

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:40:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:41
User entered '2'	System	02 Dec 2020 21:14:07

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:40:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:41
User entered 'I'	System	02 Dec 2020 21:14:07

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:40:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:41
User entered '804 (804)'	System	02 Dec 2020 21:14:07

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:40:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:38
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE, PRODUCTSYNONYM: PRILOSEC [OMEPRAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Dec 2020 18:16:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Dec 2020 18:16:51
Data point term sent to Coder	System	10 Dec 2020 18:16:09
Coding entries removed.	Phoebe Cunningham (b) (4)	10 Dec 2020 18:15:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE, PRODUCTSYNONYM: PRILOSEC [OMEPRAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Dec 2020 21:18:21
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 21:18:21
Data point term sent to Coder	System	02 Dec 2020 21:16:17
User entered 'PRILOSEC'	Kathleen Garvey (b) (4)	02 Dec 2020 21:15:25



US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:40:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:38
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'No (N)'	Kathleen Garvey (b) (4)	02 Dec 2020 21:15:25

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:40:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:38
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'dyspepsia' reason for change: Data Entry Error	Phoebe Cunningham (b) (4)	10 Dec 2020 18:15:36
User entered 'HEARTBURN'	Kathleen Garvey (b) (4)	02 Dec 2020 21:15:25

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:40:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:38
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered '20'	Kathleen Garvey (b) (4)	02 Dec 2020 21:15:25

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:40:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:38
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'mg (mg)'	Kathleen Garvey (b) (4)	02 Dec 2020 21:15:25

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:40:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:38
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered empty.	Kathleen Garvey (b) (4)	02 Dec 2020 21:15:25

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:40:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:38
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'once (ONCE)'	Kathleen Garvey (b) (4)	02 Dec 2020 21:15:25

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:40:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:38
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered empty.	Kathleen Garvey (b) (4)	02 Dec 2020 21:15:25

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:40:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:38
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'Oral (ORAL)'	Kathleen Garvey (b) (4)	02 Dec 2020 21:15:25



US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:40:32**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:38
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered empty.	Kathleen Garvey (b) (4)	02 Dec 2020 21:15:25

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:40:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:38
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered '27 Nov 2020'	Kathleen Garvey (b) (4)	02 Dec 2020 21:15:25

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:40:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:38
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered '0'	Kathleen Garvey (b) (4)	02 Dec 2020 21:15:25

**US3432641**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:40:32**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:38
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'No (N)'	Kathleen Garvey (b) (4)	02 Dec 2020 21:15:25

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:40:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:38
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered '27 Nov 2020'	Kathleen Garvey (b) (4)	02 Dec 2020 21:15:25

US3432641

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:40:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:38
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'No (N)'	Kathleen Garvey (b) (4)	02 Dec 2020 21:15:25

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:40:32**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:38
User entered empty.	System	02 Dec 2020 21:15:25

US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:40:32**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:38
User entered empty.	System	02 Dec 2020 21:15:25



US3432641

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:40:32**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:04:38
User entered empty.	System	02 Dec 2020 21:15:25

US3432641

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 11 Aug 2021 22:40:32**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:02
User entered 'No (N)'	Tenaizus Woods (b) (4)	27 Feb 2021 16:59:47
	(b) (4)	