

US3852177 (Prod: Ascension St. Vincent Birmingham)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:04:53

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US3852177

Form: Participant Creation

Data signed: (b) (4) 09 Feb 2021 10:55:35

Generated On: 10 Jun 2021 10:04:53

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Participant ID

US3852177

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

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US3852177

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 09 Feb 2021 10:55:36

Generated On: 10 Jun 2021 10:04:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 09 Feb 2021 10:55:36

Generated On: 10 Jun 2021 10:04:53

Date of Birth (MMM yyyy)	(b) (6) 1966
Age	53
Age Units	YEARS
Age (Derived)	53
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 09 Feb 2021 10:55:36

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	11 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 09 Feb 2021 10:55:36

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 09 Feb 2021 10:55:36

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Were any significant conditions reported?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 09 Feb 2021 10:55:36

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



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 09 Feb 2021 10:55:36

Generated On: 10 Jun 2021 10:04:53

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 1996
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 1996
Start Year (derived)	1996
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 09 Feb 2021 10:55:36

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Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 09 Feb 2021 10:55:36

Generated On: 10 Jun 2021 10:04:53

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 09 Feb 2021 10:55:36

Generated On: 10 Jun 2021 10:04:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	11 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	14:20 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 14:20
Height ( <i>xxx.x</i> )	72 in
Weight ( <i>xxx.x</i> )	302 lb
BMI ( <i>xxx.x</i> )	41.04420 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED FOREHEAD
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 09 Feb 2021 10:55:36

Generated On: 10 Jun 2021 10:04:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 09 Feb 2021 10:55:36

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 09 Feb 2021 10:55:36

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 09 Feb 2021 10:55:36

Generated On: 10 Jun 2021 10:04:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	VISIT1



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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 09 Feb 2021 10:55:36

Generated On: 10 Jun 2021 10:04:53

What was the date of randomization? (dd MMM yyyy) 11 SEP 2020

What was the participant's randomization number? 146275

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

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

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

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

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

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

Liver Disease Yes ☐   
 No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐   
 No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 09 Feb 2021 10:55:36

Generated On: 10 Jun 2021 10:04:53

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Feb 2021 10:55:36

Generated On: 10 Jun 2021 10:04:53

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)	11 SEP 2020
Time of assessment (00:00-23:59)	14:20 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 14:20
Temperature (xxx.x)	98 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	INFRARED FOREHEAD
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Feb 2021 10:55:36

Generated On: 10 Jun 2021 10:04:53

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)	11 SEP 2020
Time of assessment (00:00-23:59)	15:36 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 15:36
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	INFRARED FOREHEAD
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 09 Feb 2021 10:55:36

Generated On: 10 Jun 2021 10:04:53

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 09 Feb 2021 10:55:36

Generated On: 10 Jun 2021 10:04:53

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) 11 SEP 2020

What was the treatment time? (00:00-23:59) 15:06 (24 HR)

Treatment Date and Time (derived) 11 SEP 2020 15:06

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Feb 2021 10:55:36

Generated On: 10 Jun 2021 10:04:53

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 SEP 2020

Collection time (00:00-23:59)

14:55 (24 HR)

Collection date and time (derived)

11 SEP 2020 14:55

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 09 Feb 2021 10:55:36

Generated On: 10 Jun 2021 10:04:53

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:40	11 SEP 2020 14:40
Nasopharyngeal Swab 2	No		



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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 09 Feb 2021 10:55:36

Generated On: 10 Jun 2021 10:04:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

**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

98.2 °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

11 SEP 2020 15:37

PC Open Date & Time

11 SEP 2020 15:26

PC Close Date & Time

11 SEP 2020 17:56

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

**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 98.1 °F

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

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

PC Time Stamp	11 SEP 2020 20:12
PC Open Date & Time	11 SEP 2020 18:51
PC Close Date & Time	12 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 16:14

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

13 SEP 2020 12:04

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:04:53

**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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 16:34

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:04:53

**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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 18:28

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:04:53

**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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 18:11

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59



US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:04:53

**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

97.6 °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

17 SEP 2020 17:38

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 15:38

PC Open Date & Time

11 SEP 2020 15:26

PC Close Date & Time

11 SEP 2020 17:56

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

51

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 20:14

PC Open Date & Time

11 SEP 2020 18:51

PC Close Date & Time

12 SEP 2020 11:59

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

2

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 16:15

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:04:53

**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

13 SEP 2020 12:03

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 16:35

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:04:53

**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

15 SEP 2020 18:29

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:04:53

**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

16 SEP 2020 18:10

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59



US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:04:53

**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

17 SEP 2020 17:38

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

**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 ☐

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 15:38
PC Open Date & Time	11 SEP 2020 15:26
PC Close Date & Time	11 SEP 2020 17:56

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

**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 ☐

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 20:15
PC Open Date & Time	11 SEP 2020 18:51
PC Close Date & Time	12 SEP 2020 11:59

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:04:53

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 ☒

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:04:53

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 16:16
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:04:53

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 ☒



US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:04:53

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 12:02
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:04:53

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 ☒

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:04:53

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 16:35
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:04:53

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

51 of 2042

EAB) (1725)

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:04:53

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 18:29
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:04:53

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

53 of 2042

EAB) (1725)

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:04:53

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 18:10
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:04:53

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 ☒



US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:04:53

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 17:37
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3852177

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 09 Feb 2021 10:55:36

Generated On: 10 Jun 2021 10:04:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3852177

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 09 Feb 2021 10:55:36

Generated On: 10 Jun 2021 10:04:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3852177

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 09 Feb 2021 10:55:35

Generated On: 10 Jun 2021 10:04:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3852177

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 09 Feb 2021 10:55:35

Generated On: 10 Jun 2021 10:04:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3852177

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 09 Feb 2021 10:55:35

Generated On: 10 Jun 2021 10:04:53

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3852177

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 09 Feb 2021 10:55:35

Generated On: 10 Jun 2021 10:04:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3852177

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 09 Feb 2021 10:55:36

Generated On: 10 Jun 2021 10:04:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 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	VISIT2



US3852177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Feb 2021 10:55:36

Generated On: 10 Jun 2021 10:04:53

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)	6 OCT 2020
Time of assessment (00:00-23:59)	13:43 (24 HR)
Vital Signs Date and Time (derived)	6 OCT 2020 13:43
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED/FOREHEAD
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3852177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Feb 2021 10:55:36

Generated On: 10 Jun 2021 10:04:53

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)	6 OCT 2020
Time of assessment (00:00-23:59)	14:32 (24 HR)
Vital Signs Date and Time (derived)	6 OCT 2020 14:32
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED/FOREHEAD
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3852177

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Feb 2021 10:55:36

Generated On: 10 Jun 2021 10:04:53

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.*

US3852177

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 09 Feb 2021 10:55:36

Generated On: 10 Jun 2021 10:04:53

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) 6 OCT 2020

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

Treatment Date and Time (derived) 6 OCT 2020 14:01

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

What was the frequency of the study treatment dosing? ONCE

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

US3852177

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Feb 2021 10:55:36

Generated On: 10 Jun 2021 10:04:53

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

6 OCT 2020

Collection time (00:00-23:59)

14:00 (24 HR)

Collection date and time (derived)

6 OCT 2020 14:00

US3852177

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 09 Feb 2021 10:55:36

Generated On: 10 Jun 2021 10:04:53

Collection date (dd MMM yyyy)			6 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	6 OCT 2020 13:45
Nasopharyngeal Swab 2	No		

US3852177

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 09 Feb 2021 10:55:36

Generated On: 10 Jun 2021 10:04:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

**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

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 OCT 2020 14:33

PC Open Date & Time

06 OCT 2020 14:21

PC Close Date & Time

06 OCT 2020 16:51



US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

**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

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

06 OCT 2020 17:46

PC Close Date & Time

07 OCT 2020 11:59

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 OCT 2020 12:03

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:04:53

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

11 OCT 2020 09:34

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:04:53

**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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 OCT 2020 12:37

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:04:53

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**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

97.6 °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

13 OCT 2020 06:38

---

PC Open Date & Time

12 OCT 2020 12:00

---

PC Close Date & Time

13 OCT 2020 11:59

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US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 OCT 2020 14:34

PC Open Date & Time

06 OCT 2020 14:21

PC Close Date & Time

06 OCT 2020 16:51



US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

06 OCT 2020 17:46

PC Close Date & Time

07 OCT 2020 11:59

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

3

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 OCT 2020 12:02

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:04:53

**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

11 OCT 2020 09:35

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:04:53

**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

11 OCT 2020 12:38

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:04:53

**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

13 OCT 2020 06:37

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

**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 ☐



US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

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

No ☒

Yes ☐

PC Time stamp	06 OCT 2020 14:33
PC Open Date & Time	06 OCT 2020 14:21
PC Close Date & Time	06 OCT 2020 16:51

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

**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 ☐

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

06 OCT 2020 17:46

PC Close Date & Time

07 OCT 2020 11:59

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:04:53

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:04:53

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 12:01
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:04:53

**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  
EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:04:53

Yes ☐

PC Time stamp

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:04:53

Yes ☐

PC Time stamp

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:04:53

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 ☒

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:04:53

Yes <input type="checkbox"/>	
PC Time stamp	11 OCT 2020 09:35
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:04:53

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:04:53

Yes <input type="checkbox"/>	
PC Time stamp	11 OCT 2020 12:37
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:04:53

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

101 of 2042

EAB) (1725)

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:04:53

Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 06:37
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3852177

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 09 Feb 2021 10:55:35

Generated On: 10 Jun 2021 10:04:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3852177

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 09 Feb 2021 10:55:35

Generated On: 10 Jun 2021 10:04:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3852177

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 09 Feb 2021 10:55:35

Generated On: 10 Jun 2021 10:04:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3852177

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 09 Feb 2021 10:55:35

Generated On: 10 Jun 2021 10:04:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3852177

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 09 Feb 2021 10:55:35

Generated On: 10 Jun 2021 10:04:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3852177

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 09 Feb 2021 10:55:35

Generated On: 10 Jun 2021 10:04:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3852177

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 09 Feb 2021 10:55:36

Generated On: 10 Jun 2021 10:04:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3852177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Feb 2021 10:55:36

Generated On: 10 Jun 2021 10:04:53

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	19 NOV 2020
Time of assessment ( <i>00:00-23:59</i> )	09:56 (24 HR)
Vital Signs Date and Time (derived)	19 NOV 2020 09:56
Temperature ( <i>xxx.x</i> )	97.5 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED/FOREHEAD
Pulse ( <i>xxx</i> )	71 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	90 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3852177

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Feb 2021 10:55:36

Generated On: 10 Jun 2021 10:04:53

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.*



US3852177

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Feb 2021 10:55:36

Generated On: 10 Jun 2021 10:04:53

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 NOV 2020

Collection time (00:00-23:59)

10:15 (24 HR)

Collection date and time (derived)

19 NOV 2020 10:15

US3852177

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 09 Feb 2021 10:55:36

Generated On: 10 Jun 2021 10:04:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

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 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"/>

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

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26 NOV 2020 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

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	29 NOV 2020 18:31:56
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2020 23:59

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

13 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

17 DEC 2020 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	22 DEC 2020 12:35:50
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

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

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

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27 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

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31 DEC 2020 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**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

07 JAN 2021 11:59:59

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 JAN 2021 12:00:54

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**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

19 JAN 2021 12:04:26

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**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

27 JAN 2021 12:07:39

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**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

31 JAN 2021 11:57:15

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

<b>TIMEPOINT</b>	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	09 FEB 2021 18:14:56
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**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

16 FEB 2021 12:07:06

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 FEB 2021 18:18:50

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59



US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**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

28 FEB 2021 15:22:04

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	07 MAR 2021 00:03:11
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**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

16 MAR 2021 12:30:29

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 00:25:01

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

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

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

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28 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 APR 2021 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 APR 2021 12:25:35

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 APR 2021 12:44:27

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59



US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

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 checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	True
Chills	True
Cough	True
Shortness of breath	True
Difficulty breathing	True
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	True
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message 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 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	18 APR 2021 01:33:35
Patient Cloud Open Date & Time	18 APR 2021 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
144 of 2042	

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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[Patient Cloud Close Date & Time](#)

22 APR 2021 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 00:02:23

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

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

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

02 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 243

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

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

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

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 250

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

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 ☐

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**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 ☐ Yes ☐

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

30 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**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 ☐ 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 ☐

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

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

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**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 ☐

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

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27 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUL 2021 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

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

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



**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

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

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

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

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"/>

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

25 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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 ☐

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**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 ☐  
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 ☐



**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

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08 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 AUG 2021 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

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

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

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"/>

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**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 ☐

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

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29 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 SEP 2021 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

05 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

19 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

26 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

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"/>

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

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

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

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

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



**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

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"/>

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

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

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

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

14 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**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 ☐  
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 ☐

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

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21 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 NOV 2021 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

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"/>



**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

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28 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 DEC 2021 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

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"/>

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

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

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

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

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



**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

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

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

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3852177**

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

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

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

**US3852177**

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

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**Generated On: 10 Jun 2021 10:04:53**

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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16 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 JAN 2022 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**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 ☐



**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**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 ☐

**US3852177**

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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30 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 FEB 2022 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3852177**

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

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**Generated On: 10 Jun 2021 10:04:53**

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3852177**

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

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**Generated On: 10 Jun 2021 10:04:53**

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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13 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 FEB 2022 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3852177**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**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 ☐

**US3852177**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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27 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 MAR 2022 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3852177**

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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06 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAR 2022 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3852177**

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 MAR 2022 23:59

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

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

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



**US3852177**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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20 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAR 2022 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

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

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

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

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27 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAR 2022 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**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 ☐

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**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 ☐

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 APR 2022 23:59

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**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 ☐



**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**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 ☐

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

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24 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 APR 2022 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

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"/>

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

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01 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 MAY 2022 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**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 ☐  
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 ☐

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

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"/>



**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

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"/>

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Close Date & Time](#)

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26 MAY 2022 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

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

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

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29 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 JUN 2022 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

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

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

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

05 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

19 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

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 ☐

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

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26 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 JUN 2022 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**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 ☐

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

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03 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 JUL 2022 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

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"/>



**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 JUL 2022 23:59

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**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 ☐ 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 ☐

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

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24 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 JUL 2022 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

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

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

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07 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2022 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

14 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**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 ☐ 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 ☐

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

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21 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 AUG 2022 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**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 ☐ 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 ☐

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

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28 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 SEP 2022 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

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"/>



**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

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04 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 SEP 2022 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

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

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

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"/>

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

25 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

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

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



**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**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 ☐ 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 ☐

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**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 ☐  
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 ☐

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 OCT 2022 23:59

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**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 ☐

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

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23 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 OCT 2022 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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



**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

30 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

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

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

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

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06 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 NOV 2022 23:59

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US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

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"/>

**US3852177**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

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

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[Patient Cloud Open Date & Time](#)

13 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 NOV 2022 23:59

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US3852177

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 10 Jun 2021 10:04:53**

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		28 FEB 2021 05:19:54

US3852177

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 09 Feb 2021 10:55:36

Generated On: 10 Jun 2021 10:04:53

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 NOV 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3852177

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 09 Feb 2021 10:55:36

Generated On: 10 Jun 2021 10:04:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3852177

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 09 Feb 2021 10:55:35

Generated On: 10 Jun 2021 10:04:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3852177

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 09 Feb 2021 10:55:35

Generated On: 10 Jun 2021 10:04:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3852177

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 01:23:24

Generated On: 10 Jun 2021 10:04:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3852177

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 09 Feb 2021 10:55:35

Generated On: 10 Jun 2021 10:04:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3852177

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 04:37:58

Generated On: 10 Jun 2021 10:04:53

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3852177

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 04:37:58

Generated On: 10 Jun 2021 10:04:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3852177

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 20:57:56

Generated On: 10 Jun 2021 10:04:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3852177

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 20:57:56

Generated On: 10 Jun 2021 10:04:53

Were vital signs assessed? Yes ☐  
No ☒

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

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

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_



US3852177

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 20:57:56

Generated On: 10 Jun 2021 10:04:53

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.*

US3852177

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 20:57:56

Generated On: 10 Jun 2021 10:04:53

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 MAR 2021

Collection time (00:00-23:59)

10:38 (24 HR)

Collection date and time (derived)

25 MAR 2021 10:38

US3852177

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 20:57:56

Generated On: 10 Jun 2021 10:04:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3852177

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 03 May 2021 21:14:07

Generated On: 10 Jun 2021 10:04:53

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 3 MAY 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3852177

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 03 May 2021 21:14:07

Generated On: 10 Jun 2021 10:04:53

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3852177

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

Was Contact Attempted? Yes ☐  
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐  
Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

**US3852177**

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

**Form: Continuing**

**Generated On: 10 Jun 2021 10:04:53**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3852177

Folder: Covid-19 Assessment (3)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:04:53

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"/>



**US3852177**

**Folder: Covid-19 Assessment (3)**

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

**Generated On: 10 Jun 2021 10:04:53**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3852177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 09 Feb 2021 10:55:35

Generated On: 10 Jun 2021 10:04:53

Date of Contact	18 SEP 2020
Time of Contact	14:58
Date and Time of Contact (derived)	18 SEP 2020 14:58
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input checked="" type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

US3852177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 09 Feb 2021 10:55:35

Generated On: 10 Jun 2021 10:04:53

---

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

---

US3852177

Folder: Covid-19 Assessment 25 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 09 Feb 2021 10:55:35

Generated On: 10 Jun 2021 10:04:53

Date of Contact	25 SEP 2020
Time of Contact	11:10
Date and Time of Contact (derived)	25 SEP 2020 11:10
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input checked="" type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

US3852177

Folder: Covid-19 Assessment 25 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 09 Feb 2021 10:55:35

Generated On: 10 Jun 2021 10:04:53

---

[Generate Next COVID-19 Assessment](#)

Yes ☒  
No ☐

---

US3852177

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

Form: Visit Date

Data signed: (b) (4) 15 Mar 2021 04:37:58

Generated On: 10 Jun 2021 10:04:53

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3852177

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

Form: Unblinding

Data signed: (b) (4) 15 Mar 2021 04:37:58

Generated On: 10 Jun 2021 10:04:53

Date of updated informed consent (*dd MMM yyyy*) 10 FEB 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*) 10 FEB 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 \_\_\_\_\_

US3852177

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Mar 2021 04:37:58

Generated On: 10 Jun 2021 10:04:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 FEB 2021
Collection time (00:00-23:59)	08:35 (24 HR)
Collection date and time (derived)	10 FEB 2021 08:35



US3852177

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 15 Mar 2021 04:37:58

Generated On: 10 Jun 2021 10:04:53

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 FEB 2021
Collection time (00:00 - 23:59)	08:30
Collection Date and Time (derived)	10 FEB 2021 08:30

US3852177

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 09 Feb 2021 10:55:35

Generated On: 10 Jun 2021 10:04:53

---

Did the participant experience any adverse events?

Yes ☐

No ☒

---

If Yes, enter details on the Adverse Events form.

---

US3852177

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 17:17:59

Generated On: 10 Jun 2021 10:04:53

AEID

Adverse event

RED, BLISTERED RASH IN  
PERINEAL AREA; SKIN  
EPIDERMAL  
DISORDER-NON-URITICARIAL

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

28 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

13 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 17:17:59

Generated On: 10 Jun 2021 10:04:53

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

US3852177

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 17:17:59

Generated On: 10 Jun 2021 10:04:53

AEID	USA-US076-2021-MRNA-1273-P30 1000004
Adverse event	PNEUMONIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	13 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	16 APR 2021
Hospital Discharge Date (dd MMM yyyy)	19 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 17:17:59

Generated On: 10 Jun 2021 10:04:53

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 17:17:59

Generated On: 10 Jun 2021 10:04:53

AEID	
Adverse event	REFLUX
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	19 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 17:17:59

Generated On: 10 Jun 2021 10:04:53

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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	



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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 30 Apr 2021 17:17:59

Generated On: 10 Jun 2021 10:04:53

AEID	
Adverse event	
Was this a medically-attended AE?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Was this a Solicited Adverse Reaction?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Start date (dd MMM yyyy)	
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="checkbox"/> No <input type="checkbox"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="checkbox"/> Grade 2/Moderate <input type="checkbox"/> Grade 3/Severe <input type="checkbox"/> Grade 4 <input type="checkbox"/>
Is the adverse event serious?	Yes <input type="checkbox"/> No <input type="checkbox"/>
AE is serious due To (check all that apply)	
Death	
Life threatening	
Requires inpatient or prolongation of existing Hospitalization	
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 30 Apr 2021 17:17:59

Generated On: 10 Jun 2021 10:04:53

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

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 15 Mar 2021 04:37:58

Generated On: 10 Jun 2021 10:04:53

---

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

Yes ☒

No ☐

---

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

---

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 May 2021 21:14:07

Generated On: 10 Jun 2021 10:04:53

Name of Medication LOSARTAN

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 May 2021 21:14:07

Generated On: 10 Jun 2021 10:04:53

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 May 2021 21:14:07

Generated On: 10 Jun 2021 10:04:53

Name of Medication MONTELUKAST

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 May 2021 21:14:07

Generated On: 10 Jun 2021 10:04:53

	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) _____		
Start date completely unknown		True
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"/>

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 May 2021 21:14:07

Generated On: 10 Jun 2021 10:04:53

Name of Medication ZOLPIDEM TARTRATE

Prophylaxis Yes ☐  
No ☒

Indication INSOMNIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 May 2021 21:14:07

Generated On: 10 Jun 2021 10:04:53

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 May 2021 21:14:07

Generated On: 10 Jun 2021 10:04:53

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 May 2021 21:14:07

Generated On: 10 Jun 2021 10:04:53

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 May 2021 21:14:07

Generated On: 10 Jun 2021 10:04:53

Name of Medication TRIAMCINOLONE CREAM 0.05%

Prophylaxis Yes ☐  
No ☒

Indication RASH IN PERINEAL  
AREA-NON-URTICARIAL

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☒  
Subcutaneous ☐  
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 May 2021 21:14:07

Generated On: 10 Jun 2021 10:04:53

	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)	29 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	13 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 May 2021 21:14:07

Generated On: 10 Jun 2021 10:04:53

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication FLU SHOT

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 May 2021 21:14:07

Generated On: 10 Jun 2021 10:04:53

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 May 2021 21:14:07

Generated On: 10 Jun 2021 10:04:53

Name of Medication BABY ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication BLOOD THINNER

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 May 2021 21:14:07

Generated On: 10 Jun 2021 10:04:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 May 2021 21:14:07

Generated On: 10 Jun 2021 10:04:53

Name of Medication PEPCID

Prophylaxis Yes ☐  
No ☒

Indication REFLUX

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 May 2021 21:14:07

Generated On: 10 Jun 2021 10:04:53

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 May 2021 21:14:07

Generated On: 10 Jun 2021 10:04:53

Name of Medication	BRIO
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	PNEUMONIA
Dose per administration	UNKNOWN
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	UNKNOWN
Frequency	once daily <input type="radio"/> twice daily <input checked="" type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 May 2021 21:14:07

Generated On: 10 Jun 2021 10:04:53

	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)		19 APR 2021
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)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 03 May 2021 21:14:07

Generated On: 10 Jun 2021 10:04:53

Name of Medication CEFDINIR

Prophylaxis Yes ☐  
No ☒

Indication PNEUMONIA

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 03 May 2021 21:14:07

Generated On: 10 Jun 2021 10:04:53

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	19 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		19 APR 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 03 May 2021 21:14:07

Generated On: 10 Jun 2021 10:04:53

Name of Medication PREDNISONE

Prophylaxis Yes ☐  
No ☒

Indication PNEUMONIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 03 May 2021 21:14:07

Generated On: 10 Jun 2021 10:04:53

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	19 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	26 APR 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 03 May 2021 21:14:07

Generated On: 10 Jun 2021 10:04:53

Name of Medication PNEUMONIA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication PREVENTION OF PNEUMONIA

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 03 May 2021 21:14:07

Generated On: 10 Jun 2021 10:04:53

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

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Feb 2021 10:55:35

Generated On: 10 Jun 2021 10:04:53

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:04:53

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:04:53

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 ☐

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Folder: SAE USA-US076-2021-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 30 Apr 2021 17:17:59

Generated On: 10 Jun 2021 10:04:53

SAEID	USA-US076-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LELAND
Investigator's Last Name	ALLEN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3852177

Folder: SAE USA-US076-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 30 Apr 2021 17:17:59

Generated On: 10 Jun 2021 10:04:53

SAEID	USA-US076-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LELAND
Investigator's Last Name	ALLEN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	19/APR/2021 16:39
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3852177

Folder: SAE USA-US076-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 30 Apr 2021 17:17:59

Generated On: 10 Jun 2021 10:04:53

SAEID	USA-US076-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	LELAND
Investigator's Last Name	ALLEN
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	30/APR/2021 09:40
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3852177 (Prod: Ascension St. Vincent Birmingham)

**US3852177**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 10:04:53**

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:41:13
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'US3852177'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 19:00:29

US3852177

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:04:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:08:27
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 20:19:07

US3852177

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:08:29
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '11 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 19:00:30

US3852177

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:04:53

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 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:08:30
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	11 Sep 2020 20:19:07

**US3852177**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:04:53**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
User entered 'SCRN'	System	11 Sep 2020 20:19:07

US3852177

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:04:53

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:09:24
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User closed query 'Per CDM: Please fill in this form. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 15:22:00
Query 'Per CDM: Please fill in this form. Thank you.' answered with 'Complete' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 21:34:11
User opened query 'Per CDM: Please fill in this form. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 09:06:42
User entered (b) (6) 1966'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 19:00:31



US3852177

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:04:53

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:09:22
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '53'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:33:56

**US3852177**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:04:53**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
User entered 'YEARS'	System	18 Sep 2020 21:33:56

**US3852177**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:04:53**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
User entered '53'	System	11 Sep 2020 20:27:37

US3852177

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:04:53

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:09:20
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Male (M)'	(b) (4), (b) (6)	18 Sep 2020 21:33:56

US3852177

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:04:53

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:09:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	18 Sep 2020 21:33:56

**US3852177**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:04:53**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:09:46
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 21:33:56

US3852177

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:04:53

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:09:37
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'I'	(b) (4), (b) (6)	18 Sep 2020 21:33:56

**US3852177**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:04:53**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:09:48
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 21:33:56



**US3852177**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:04:53**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:09:50
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 21:33:56

**US3852177**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:04:53**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:09:52
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 21:33:56

US3852177

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:04:53

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:09:53
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 21:33:56

US3852177

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:04:53

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:09:55
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 21:33:56

**US3852177**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:04:53**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:09:56
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 21:33:56

**US3852177**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:04:53**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:09:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 21:33:56

US3852177

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:04:53

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:29:46
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:27:37

US3852177

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
User entered 'Sep 2020'	System	11 Sep 2020 20:27:37



**US3852177**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 10:04:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
User entered '2020'	System	11 Sep 2020 20:27:37

**US3852177**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 10:04:53**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:29:47
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	11 Sep 2020 20:27:37

US3852177

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:29:49
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 20:27:37

**US3852177**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 10:04:53**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:29:51
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 20:27:37

US3852177

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:04:53

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:29:53
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 20:27:37

US3852177

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:04:53

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:29:55
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 20:27:37

US3852177

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:04:53

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:29:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 19:00:30

US3852177

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:04:53

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
User entered 'I'	System	11 Sep 2020 20:27:44



US3852177

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:30:18
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:27:44

US3852177

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:04:53

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:22:35
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 21:34:33

US3852177

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:04:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:23:04
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 21:35:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 21:35:36
Data point term sent to Coder	System	18 Sep 2020 21:34:57
User entered 'Hypertension'	(b) (4), (b) (6)	18 Sep 2020 21:34:53

**US3852177**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 10:04:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:23:04
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'UN UNK 2019'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:34:53

**US3852177**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 10:04:53**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:23:04
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 21:34:53

US3852177

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:04:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:23:04
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Sep 2020 21:35:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 21:35:04
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 21:35:04
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 21:34:53
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 21:34:53

**US3852177**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 10:04:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:23:04
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 21:34:53

**US3852177**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 10:04:53**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:23:04
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 21:34:53



US3852177

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:04:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
User entered 'Jan 2019'	System	18 Sep 2020 21:34:53

US3852177

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:04:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
User entered '2019'	System	18 Sep 2020 21:34:53

US3852177

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
User entered empty.	System	18 Sep 2020 21:34:53

**US3852177**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 10:04:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
User entered empty.	System	18 Sep 2020 21:34:53

US3852177

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:04:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:23:08
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	18 Sep 2020 21:36:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 21:36:37
Data point term sent to Coder	System	18 Sep 2020 21:35:59
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	18 Sep 2020 21:35:39

US3852177

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:23:08
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'UN UNK 1996'	(b) (4), (b) (6)	18 Sep 2020 21:35:39

US3852177

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:04:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:23:08
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 21:35:39

**US3852177**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 10:04:53**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:23:08
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:35:39



**US3852177**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 10:04:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:23:08
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 21:35:39

**US3852177**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 10:04:53**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:23:08
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 21:35:39

US3852177

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:04:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
User entered 'Jan 1996'	System	18 Sep 2020 21:35:39

US3852177

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:04:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
User entered '1996'	System	18 Sep 2020 21:35:39

US3852177

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
User entered empty.	System	18 Sep 2020 21:35:39

**US3852177**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 10:04:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
User entered empty.	System	18 Sep 2020 21:35:39

US3852177

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:04:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:23:09
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 21:36:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 21:36:37
Data point term sent to Coder	System	18 Sep 2020 21:35:59
User entered 'Insomnia'	(b) (4), (b) (6)	18 Sep 2020 21:35:57

**US3852177**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 10:04:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:23:09
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'UN UNK 1995'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:35:57



**US3852177**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 10:04:53**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:23:09
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 21:35:57

US3852177

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:04:53

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:23:09
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Sep 2020 21:36:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 21:36:04
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 21:36:04
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 21:35:57
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 21:35:57

**US3852177**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 10:04:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:23:09
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 21:35:57

**US3852177**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 10:04:53**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:23:09
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 21:35:57

US3852177

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:04:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
User entered 'Jan 1995'	System	18 Sep 2020 21:35:57

US3852177

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:04:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
User entered '1995'	System	18 Sep 2020 21:35:57

US3852177

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
User entered empty.	System	18 Sep 2020 21:35:57

**US3852177**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 10:04:53**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
User entered empty.	System	18 Sep 2020 21:35:57



US3852177

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:04:53

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:23:13
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 21:38:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 21:38:40
Data point term sent to Coder	System	18 Sep 2020 21:37:00
User entered 'Asthma'	(b) (4), (b) (6)	18 Sep 2020 21:36:22

US3852177

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:23:13
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'UN UNK 2019'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:36:22

US3852177

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:04:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:23:13
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 21:36:22

**US3852177**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 10:04:53**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:23:13
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 21:36:22

US3852177

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:23:13
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 21:36:22

US3852177

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:04:53

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:23:13
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 21:36:22

US3852177

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:04:53

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
User entered 'Jan 2019'	System	18 Sep 2020 21:36:22

US3852177

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:04:53

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
User entered '2019'	System	18 Sep 2020 21:36:22



US3852177

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
User entered empty.	System	18 Sep 2020 21:36:22

US3852177

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
User entered empty.	System	18 Sep 2020 21:36:22

US3852177

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:10:49
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 22:00:33

US3852177

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:10:51
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:00:33

**US3852177**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:04:53**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:11:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '14:20'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 22:00:33

US3852177

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
User entered '11 Sep 2020 14:20'	System	18 Sep 2020 22:00:33

US3852177

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:11:36
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '72' in	(b) (4), (b) (6)	18 Sep 2020 22:00:33
DataPoint set to visible.	System	11 Sep 2020 20:27:44

US3852177

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:11:38
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '302' lb	(b) (4), (b) (6)	18 Sep 2020 22:00:33
DataPoint set to visible.	System	11 Sep 2020 20:27:44



US3852177

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
User entered '41.04420'	System	18 Sep 2020 22:00:33
DataPoint set to visible.	System	11 Sep 2020 20:27:44

**US3852177**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:04:53**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
User entered 'kg/m2'	System	18 Sep 2020 22:00:33
DataPoint set to visible.	System	11 Sep 2020 20:27:44

US3852177

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:45:19
Query 'Per Source Temp recorded as 98 degrees F' canceled (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 03:44:55
User opened query 'Per Source Temp recorded as 98 degrees F' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 03:12:33
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Nov 2020 21:22:54
User entered '98' F	(b) (4), (b) (6)	18 Sep 2020 22:00:33

US3852177

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:45:20
Query 'Per Source Temp recorded route of measurement infared/forehead' canceled (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 03:44:59
User opened query 'Per Source Temp recorded route of measurement infared/forehead' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 03:13:19
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Other (Other)'	(b) (4), (b) (6)	18 Sep 2020 22:00:33

US3852177

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:45:22
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Infrared Forehead'	(b) (4), (b) (6)	18 Sep 2020 22:00:33

US3852177

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:45:24
Query 'Per Source pulse recorded as 69' canceled (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 03:45:02
User opened query 'Per Source pulse recorded as 69' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 03:14:38
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Nov 2020 21:22:54
User entered '69'	(b) (4), (b) (6)	18 Sep 2020 22:00:33

**US3852177**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:04:53**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
User entered 'bpm'	System	18 Sep 2020 22:00:33

US3852177

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:45:27
Query 'per source rr recorded as 16' canceled (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 03:45:03
User opened query 'per source rr recorded as 16' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 03:15:01
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Nov 2020 21:22:54
User entered '16'	(b) (4), (b) (6)	18 Sep 2020 22:00:33



US3852177

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
User entered 'breaths/min'	System	18 Sep 2020 22:00:33

US3852177

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:45:29
Query 'per source systolic BP recorded as 137' canceled (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 03:45:06
User opened query 'per source systolic BP recorded as 137' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 03:15:29
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Nov 2020 21:22:54
User entered '137'	(b) (4), (b) (6)	18 Sep 2020 22:00:33

US3852177

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
User entered 'mmHg'	System	18 Sep 2020 22:00:33

US3852177

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:45:32
Query 'per source diastolic BP recorded as 82' canceled (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 03:45:10
User opened query 'per source diastolic BP recorded as 82' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 03:15:56
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Nov 2020 21:22:54
User entered '82'	(b) (4), (b) (6)	18 Sep 2020 22:00:33

US3852177

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
User entered 'mmHg'	System	18 Sep 2020 22:00:33

US3852177

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12

US3852177

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12

US3852177

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:24:17
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 20:28:05



US3852177

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:24:19
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:28:05

US3852177

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:53

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:25:20
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 20:32:03

US3852177

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:53

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:25:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 20:32:03

US3852177

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:53

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:25:23
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:32:03

US3852177

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:53

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:25:26
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:32:03

US3852177

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:53

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:25:28
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 20:32:03

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:53

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:25:30
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:32:03

US3852177

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:53

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:25:31
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:32:03



US3852177

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:53

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:25:33
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 20:32:03

US3852177

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:53

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:25:37
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 20:32:03

US3852177

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:53

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:25:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:32:03

US3852177

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:53

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:25:43
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:32:03

US3852177

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:53

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:25:44
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 20:32:03

US3852177

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:53

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:25:46
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 20:32:03

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:53

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:32:03

US3852177

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:27:03
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 03:26:01
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:25:51
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:32:03



US3852177

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:53

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:27:05
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 03:26:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:25:53
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:32:03

US3852177

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:53

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:27:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 03:26:05
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:25:55
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:32:03

US3852177

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:53

**Resides in low density, multi-family setting without** (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:27:08
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '0'	(b) (4), (b) (6)	11 Sep 2020 20:32:03

US3852177

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:53

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:27:12
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'l'	(b) (4), (b) (6)	11 Sep 2020 20:32:03

**US3852177**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 10:04:53**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:32:03

US3852177

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:04:53

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:27:14
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 20:32:03

US3852177

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:04:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:36:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:28:31

US3852177

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:04:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:36:07
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:28:31



US3852177

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:04:53

[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 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:36:08
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Home (Home)'	(b) (4), (b) (6)	11 Sep 2020 20:28:31

US3852177

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:04:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
User entered 'VISIT1'	System	11 Sep 2020 20:28:31

US3852177

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:37:38
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '11 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 19:44:46

US3852177

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:04:53

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:37:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '146275'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 19:44:46

US3852177

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:04:53

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:37:49
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 19:44:46

US3852177

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:04:53

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:38:19
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 03:38:03
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:37:51
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:29:12

US3852177

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:04:53

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:38:27
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 20:29:12

US3852177

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:04:53

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:38:25
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:29:12



US3852177

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:04:53

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:38:31
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	(b) (4), (b) (6)	11 Sep 2020 20:29:12

US3852177

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:04:53

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:38:33
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:29:12

US3852177

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:04:53

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:04
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 03:39:26
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:38:36
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 15:55:04
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 06:14:54
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:14:52

US3852177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:04:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:41:28
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 03:41:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:40:12
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User closed query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:57:55
Query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	17 Oct 2020 04:57:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	17 Oct 2020 04:57:30
User opened query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 13:58:33
User entered '72' in	(b) (4), (b) (6)	18 Sep 2020 21:58:13

US3852177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:04:53

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:41:30
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 03:41:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:40:13
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	17 Oct 2020 04:57:30
User entered '302' lb	(b) (4), (b) (6)	18 Sep 2020 21:58:13

US3852177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:04:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:41:28
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 03:41:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:40:12
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User closed query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:57:55
Query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	17 Oct 2020 04:57:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	17 Oct 2020 04:57:30
User opened query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 13:58:33
User entered '72' in	(b) (4), (b) (6)	18 Sep 2020 21:58:13

US3852177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:04:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:41:30
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 03:41:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:40:13
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	17 Oct 2020 04:57:30
User entered '302' lb	(b) (4), (b) (6)	18 Sep 2020 21:58:13

US3852177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	18 Sep 2020 21:58:13



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:40:43
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:58:13

US3852177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:40:43
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:58:13

US3852177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:40:43
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '14:20'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:58:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
User entered '11 Sep 2020 14:20'	System	18 Sep 2020 21:58:13

US3852177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:40:43
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '98' F	(b) (4), (b) (6)	18 Sep 2020 21:58:13

US3852177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:40:43
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:58:13

US3852177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:40:43
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Infrared Forehead'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:58:13

US3852177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:40:43
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '69'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:58:13



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
User entered 'bpm'	System	18 Sep 2020 21:58:13

US3852177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:40:43
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '16'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:58:13

US3852177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
User entered 'breaths/min'	System	18 Sep 2020 21:58:13

US3852177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:40:43
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '137'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:58:13

US3852177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
User entered 'mmHg'	System	18 Sep 2020 21:58:13

US3852177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:40:43
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '82'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:58:13

US3852177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
User entered 'mmHg'	System	18 Sep 2020 21:58:13

US3852177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:04:53

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:41:28
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 03:41:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:40:12
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User closed query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Oct 2020 14:57:55
Query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	17 Oct 2020 04:57:39
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	17 Oct 2020 04:57:30
User opened query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight and remove the units accordingly. ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 13:58:33
User entered '72' in	(b) (4), (b) (6)	18 Sep 2020 21:58:13



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:04:53

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:41:30
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 03:41:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:40:13
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	17 Oct 2020 04:57:30
User entered '302' lb	(b) (4), (b) (6)	18 Sep 2020 21:58:13

US3852177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	18 Sep 2020 21:58:13

US3852177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:40:46
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:58:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:40:46
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:58:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:40:46
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '15:36'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:58:13

US3852177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
User entered '11 Sep 2020 15:36'	System	18 Sep 2020 21:58:13

US3852177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:40:46
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	18 Sep 2020 21:58:57
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	18 Sep 2020 21:58:57
User entered '98.2' F reason for change: Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 21:58:57
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Sep 2020 21:58:13
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 21:58:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:40:46
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:58:13



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:40:46
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Infrared Forehead'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:58:13

US3852177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:40:46
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '69'	(b) (4), (b) (6)	18 Sep 2020 21:58:13

US3852177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
User entered 'bpm'	System	18 Sep 2020 21:58:13

US3852177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:40:46
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '18'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:58:13

US3852177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
User entered 'breaths/min'	System	18 Sep 2020 21:58:13

US3852177

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:40:46
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '138'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:58:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
User entered 'mmHg'	System	18 Sep 2020 21:58:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:40:46
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '90'	(b) (4), (b) (6)	18 Sep 2020 21:58:13



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
User entered 'mmHg'	System	18 Sep 2020 21:58:13

US3852177

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:42:48
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:59:07

US3852177

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:42:50
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:59:07

US3852177

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:04:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:43:19
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:30:19

US3852177

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:04:53

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:43:20
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 20:30:19

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:43:22
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 20:30:19

US3852177

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:04:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 20:30:19

US3852177

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:04:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:43:35
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:30:19



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:04:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:43:36
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '15:06'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:30:19

US3852177

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:04:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
User entered '11 Sep 2020 15:06'	System	11 Sep 2020 20:30:19

US3852177

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:04:53

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:43:38
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 20:30:19

US3852177

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:04:53

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:43:40
User entered 'ONCE'	System	11 Sep 2020 20:30:19

US3852177

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:04:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 20:30:19

US3852177

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:48:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:36:59

US3852177

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:48:42
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:36:59

US3852177

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:48:44
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '14:55'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:36:59



US3852177

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
User entered '11 Sep 2020 14:55'	System	18 Sep 2020 21:36:59

US3852177

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:04:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:01:30
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:37:19

**US3852177**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 10:04:53**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	18 Sep 2020 21:37:19

US3852177

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:04:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:48:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:37:19

US3852177

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:04:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:48:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '14:40'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 21:37:19

US3852177

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:04:53

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
User entered '11 Sep 2020 14:40'	System	18 Sep 2020 21:37:19

US3852177

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:04:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	18 Sep 2020 21:37:19

US3852177

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:04:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:01:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 21:37:19



**US3852177**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 10:04:53**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:01:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 21:37:19

US3852177

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:04:53

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
User entered empty.	System	18 Sep 2020 21:37:19

US3852177

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:04:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:48:52
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	18 Sep 2020 17:24:03

US3852177

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:04:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:57
User entered 'I'	System	18 Sep 2020 17:24:03

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
Data entry locked.	System	11 Sep 2020 20:30:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-11T15:35:55', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '91d67dce-7f70-4ae3-bceb-910771272705' User entered 'Yes (Y)'	System	11 Sep 2020 20:37:45
	System	11 Sep 2020 20:37:45

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-11T15:37:30', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '91d67dce-7f70-4ae3-bceb-910771272705' User entered '98.2'	System	11 Sep 2020 20:37:45
	System	11 Sep 2020 20:37:45

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-11T15:37:36', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '91d67dce-7f70-4ae3-bceb-910771272705'	System	11 Sep 2020 20:37:45
User entered 'No (N)'	System	11 Sep 2020 20:37:45



US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-11T15:37:41', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '91d67dce-7f70-4ae3-bceb-910771272705'	System	11 Sep 2020 20:37:45
User entered '11 Sep 2020 15:37'	System	11 Sep 2020 20:37:45

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
User entered '11 Sep 2020 15:26'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
User entered '11 Sep 2020 17:56'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
Data entry locked.	System	11 Sep 2020 20:30:19
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-11T20:11:03', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '9157cc5e-1839-49b6-a1d7-c01685679582' User entered 'Yes (Y)'	System	12 Sep 2020 01:12:41
	System	12 Sep 2020 01:12:41

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-11T20:12:22', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '9157cc5e-1839-49b6-a1d7-c01685679582' User entered '98.1'	System	12 Sep 2020 01:12:41
	System	12 Sep 2020 01:12:41

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-11T20:12:31', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '9157cc5e-1839-49b6-a1d7-c01685679582'	System	12 Sep 2020 01:12:41
User entered 'No (N)'	System	12 Sep 2020 01:12:41

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-11T20:12:38', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '9157cc5e-1839-49b6-a1d7-c01685679582'	System	12 Sep 2020 01:12:41
User entered '11 Sep 2020 20:12'	System	12 Sep 2020 01:12:41



US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
User entered '11 Sep 2020 18:51'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
Data entry locked.	System	11 Sep 2020 20:30:19
User entered 'Day 2'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:04:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-12T16:13:43', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'db256ced-7f42-4b6a-b63b-b84ace1d16b8' User entered 'Yes (Y)'	System	12 Sep 2020 21:14:05
	System	12 Sep 2020 21:14:05

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:04:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-12T16:13:49', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'db256ced-7f42-4b6a-b63b-b84ace1d16b8' User entered '98.7'	System	12 Sep 2020 21:14:05
	System	12 Sep 2020 21:14:05

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-12T16:13:54', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'db256ced-7f42-4b6a-b63b-b84ace1d16b8'	System	12 Sep 2020 21:14:05
User entered 'No (N)'	System	12 Sep 2020 21:14:05

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:04:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-12T16:14:02', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'db256ced-7f42-4b6a-b63b-b84ace1d16b8' User entered '12 Sep 2020 16:14'	System	12 Sep 2020 21:14:05
	System	12 Sep 2020 21:14:05

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 20:30:19



US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
Data entry locked.	System	11 Sep 2020 20:30:19
User entered 'Day 3'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:04:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-13T12:03:39', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '50cfe9d1-61a9-4db4-9314-e3f4030b4cd0' User entered 'Yes (Y)'	System	13 Sep 2020 17:04:30
	System	13 Sep 2020 17:04:30

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:04:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-13T12:04:18', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '50cfe9d1-61a9-4db4-9314-e3f4030b4cd0' User entered '97.5'	System	13 Sep 2020 17:04:30
	System	13 Sep 2020 17:04:30

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-13T12:04:24', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '50cfe9d1-61a9-4db4-9314-e3f4030b4cd0'	System	13 Sep 2020 17:04:30
User entered 'No (N)'	System	13 Sep 2020 17:04:30

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:04:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-13T12:04:29', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '50cfe9d1-61a9-4db4-9314-e3f4030b4cd0' User entered '13 Sep 2020 12:04'	System	13 Sep 2020 17:04:30
	System	13 Sep 2020 17:04:30

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 20:30:19



US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
Data entry locked.	System	11 Sep 2020 20:30:19
User entered 'Day 4'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:04:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-14T16:34:04', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'a1987af4-6e44-49c6-8294-9e98e5a070cb' User entered 'Yes (Y)'	System	14 Sep 2020 21:34:35
	System	14 Sep 2020 21:34:35

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:04:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-14T16:34:14', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'a1987af4-6e44-49c6-8294-9e98e5a070cb' User entered '97.4'	System	14 Sep 2020 21:34:35
	System	14 Sep 2020 21:34:35

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-14T16:34:24', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'a1987af4-6e44-49c6-8294-9e98e5a070cb' User entered 'No (N)'	System	14 Sep 2020 21:34:35
	System	14 Sep 2020 21:34:35

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:04:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-14T16:34:30', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'a1987af4-6e44-49c6-8294-9e98e5a070cb' User entered '14 Sep 2020 16:34'	System	14 Sep 2020 21:34:35
	System	14 Sep 2020 21:34:35

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
Data entry locked.	System	11 Sep 2020 20:30:19
User entered 'Day 5'	System	11 Sep 2020 20:30:19



US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:04:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-15T18:28:25', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '05bc0142-160c-4df1-9654-985e32e21ba7' User entered 'Yes (Y)'	System	15 Sep 2020 23:28:52
	System	15 Sep 2020 23:28:52

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:04:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-15T18:28:41', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '05bc0142-160c-4df1-9654-985e32e21ba7' User entered '97.7'	System	15 Sep 2020 23:28:52
	System	15 Sep 2020 23:28:52

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-15T18:28:47', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '05bc0142-160c-4df1-9654-985e32e21ba7' User entered 'No (N)'	System	15 Sep 2020 23:28:52
	System	15 Sep 2020 23:28:52

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:04:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-15T18:28:51', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '05bc0142-160c-4df1-9654-985e32e21ba7' User entered '15 Sep 2020 18:28'	System	15 Sep 2020 23:28:52
	System	15 Sep 2020 23:28:52

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
Data entry locked.	System	11 Sep 2020 20:30:19
User entered 'Day 6'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:04:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-16T18:10:54', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'ba861900-bc6e-456e-9160-714a97a7dae6' User entered 'Yes (Y)'	System	16 Sep 2020 23:11:12
	System	16 Sep 2020 23:11:12



US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:04:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-16T18:11:03', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'ba861900-bc6e-456e-9160-714a97a7dae6' User entered '98.0'	System	16 Sep 2020 23:11:12
	System	16 Sep 2020 23:11:12

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-16T18:11:07', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'ba861900-bc6e-456e-9160-714a97a7dae6' User entered 'No (N)'	System	16 Sep 2020 23:11:12
	System	16 Sep 2020 23:11:12

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:04:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-16T18:11:10', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'ba861900-bc6e-456e-9160-714a97a7dae6' User entered '16 Sep 2020 18:11'	System	16 Sep 2020 23:11:12
	System	16 Sep 2020 23:11:12

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
Data entry locked.	System	11 Sep 2020 20:30:19
User entered 'Day 7'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:04:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-17T17:38:27', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '0600efc9-ceec-46b3-bf4b-e8d00133e7c5' User entered 'Yes (Y)'	System	17 Sep 2020 22:38:50
	System	17 Sep 2020 22:38:50

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:04:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-17T17:38:38', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '0600efc9-ceec-46b3-bf4b-e8d00133e7c5' User entered '97.6'	System	17 Sep 2020 22:38:50
	System	17 Sep 2020 22:38:50



US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-17T17:38:46', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '0600efc9-ceec-46b3-bf4b-e8d00133e7c5'	System	17 Sep 2020 22:38:50
User entered 'No (N)'	System	17 Sep 2020 22:38:50

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:04:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-17T17:38:48', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '0600efc9-ceec-46b3-bf4b-e8d00133e7c5'	System	17 Sep 2020 22:38:50
User entered '17 Sep 2020 17:38'	System	17 Sep 2020 22:38:50

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
Data entry locked.	System	11 Sep 2020 20:30:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-11T15:37:50', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'a8c5465e-a875-4824-b78d-bb06fc15b426'	System	11 Sep 2020 20:38:10
User entered 'None (1)'	System	11 Sep 2020 20:38:10

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-11T15:37:55', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'a8c5465e-a875-4824-b78d-bb06fc15b426' User entered 'No (N)'	System	11 Sep 2020 20:38:10
	System	11 Sep 2020 20:38:10

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-11T15:37:58', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'a8c5465e-a875-4824-b78d-bb06fc15b426'	System	11 Sep 2020 20:38:10
User entered 'No (N)'	System	11 Sep 2020 20:38:10



US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-11T15:38:04', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'a8c5465e-a875-4824-b78d-bb06fc15b426'	System	11 Sep 2020 20:38:10
User entered 'None (1)'	System	11 Sep 2020 20:38:10

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-11T15:38:07', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'a8c5465e-a875-4824-b78d-bb06fc15b426' User entered '11 Sep 2020 15:38'	System	11 Sep 2020 20:38:10
	System	11 Sep 2020 20:38:10

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '11 Sep 2020 15:26'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '11 Sep 2020 17:56'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
Data entry locked.	System	11 Sep 2020 20:30:19
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-11T20:13:09', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '9ac80d38-459f-41d7-ab10-5e028fcf17e6' User entered 'None (1)'	System	12 Sep 2020 01:14:46
	System	12 Sep 2020 01:14:46

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-11T20:13:13', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '9ac80d38-459f-41d7-ab10-5e028fcf17e6'	System	12 Sep 2020 01:14:46
User entered 'No (N)'	System	12 Sep 2020 01:14:46

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-11T20:13:17', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '9ac80d38-459f-41d7-ab10-5e028fcf17e6'	System	12 Sep 2020 01:14:46
User entered 'Yes (Y)'	System	12 Sep 2020 01:14:46



US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-11T20:14:32', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '9ac80d38-459f-41d7-ab10-5e028fcf17e6' User entered '51'	System	12 Sep 2020 01:14:46
	System	12 Sep 2020 01:14:46

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-11T20:14:41', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '9ac80d38-459f-41d7-ab10-5e028fcf17e6'	System	12 Sep 2020 01:14:46
User entered 'None (1)'	System	12 Sep 2020 01:14:46

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-11T20:14:44', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '9ac80d38-459f-41d7-ab10-5e028fcf17e6'	System	12 Sep 2020 01:14:46
User entered '11 Sep 2020 20:14'	System	12 Sep 2020 01:14:46

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '11 Sep 2020 18:51'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
Data entry locked.	System	11 Sep 2020 20:30:19
User entered 'Day 2'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:04:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-12T16:14:47', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '6572146c-bbcd-4120-b3a8-945e381e45a5'	System	12 Sep 2020 21:15:30
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 21:15:30

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:04:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-12T16:14:52', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '6572146c-bbcd-4120-b3a8-945e381e45a5' User entered 'No (N)'	System	12 Sep 2020 21:15:30
	System	12 Sep 2020 21:15:30



US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-12T16:15:02', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '6572146c-bbcd-4120-b3a8-945e381e45a5' User entered 'Yes (Y)'	System	12 Sep 2020 21:15:30
	System	12 Sep 2020 21:15:30

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:04:53

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-12T16:15:19', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '6572146c-bbcd-4120-b3a8-945e381e45a5' User entered '2'	System	12 Sep 2020 21:15:30
	System	12 Sep 2020 21:15:30

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:04:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-12T16:15:25', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '6572146c-bbcd-4120-b3a8-945e381e45a5' User entered 'None (1)'	System	12 Sep 2020 21:15:30
	System	12 Sep 2020 21:15:30

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:04:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-12T16:15:28', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '6572146c-bbcd-4120-b3a8-945e381e45a5' User entered '12 Sep 2020 16:15'	System	12 Sep 2020 21:15:30
	System	12 Sep 2020 21:15:30

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
Data entry locked.	System	11 Sep 2020 20:30:19
User entered 'Day 3'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:04:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-13T12:03:07', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'd16945d8-87aa-48b8-8024-0022130cfe0a' User entered 'None (1)'	System	13 Sep 2020 17:03:48
	System	13 Sep 2020 17:03:48



US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:04:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-13T12:03:12', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'd16945d8-87aa-48b8-8024-0022130cfe0a' User entered 'No (N)'	System	13 Sep 2020 17:03:48
	System	13 Sep 2020 17:03:48

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-13T12:03:20', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'd16945d8-87aa-48b8-8024-0022130cfe0a' User entered 'No (N)'	System	13 Sep 2020 17:03:48
	System	13 Sep 2020 17:03:48

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:04:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-13T12:03:28', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'd16945d8-87aa-48b8-8024-0022130cfe0a' User entered 'None (1)'	System	13 Sep 2020 17:03:48
	System	13 Sep 2020 17:03:48

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:04:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-13T12:03:31', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'd16945d8-87aa-48b8-8024-0022130cfe0a' User entered '13 Sep 2020 12:03'	System	13 Sep 2020 17:03:48
	System	13 Sep 2020 17:03:48

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
Data entry locked.	System	11 Sep 2020 20:30:19
User entered 'Day 4'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:04:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-14T16:35:21', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '1ddd9ef8-0183-4722-9fe1-d2d5d397cd76'	System	14 Sep 2020 21:35:47
User entered 'None (1)'	System	14 Sep 2020 21:35:47



US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:04:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-14T16:35:26', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '1ddd9ef8-0183-4722-9fe1-d2d5d397cd76' User entered 'No (N)'	System	14 Sep 2020 21:35:47
	System	14 Sep 2020 21:35:47

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-14T16:35:30', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '1ddd9ef8-0183-4722-9fe1-d2d5d397cd76' User entered 'No (N)'	System	14 Sep 2020 21:35:47
	System	14 Sep 2020 21:35:47

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:04:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-14T16:35:40', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '1ddd9ef8-0183-4722-9fe1-d2d5d397cd76'	System	14 Sep 2020 21:35:47
User entered 'None (1)'	System	14 Sep 2020 21:35:47

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:04:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-14T16:35:44', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '1ddd9ef8-0183-4722-9fe1-d2d5d397cd76' User entered '14 Sep 2020 16:35'	System	14 Sep 2020 21:35:47
	System	14 Sep 2020 21:35:47

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
Data entry locked.	System	11 Sep 2020 20:30:19
User entered 'Day 5'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:04:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-15T18:29:21', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '15df6500-a95c-40ef-b5d2-e50a9b07aa04'	System	15 Sep 2020 23:29:38
User entered 'None (1)'	System	15 Sep 2020 23:29:38



US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:04:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-15T18:29:25', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '15df6500-a95c-40ef-b5d2-e50a9b07aa04'	System	15 Sep 2020 23:29:38
User entered 'No (N)'	System	15 Sep 2020 23:29:38

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-15T18:29:28', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '15df6500-a95c-40ef-b5d2-e50a9b07aa04'	System	15 Sep 2020 23:29:38
User entered 'No (N)'	System	15 Sep 2020 23:29:38

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:04:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-15T18:29:32', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '15df6500-a95c-40ef-b5d2-e50a9b07aa04'	System	15 Sep 2020 23:29:38
User entered 'None (1)'	System	15 Sep 2020 23:29:38

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:04:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-15T18:29:35', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '15df6500-a95c-40ef-b5d2-e50a9b07aa04' User entered '15 Sep 2020 18:29'	System	15 Sep 2020 23:29:38
	System	15 Sep 2020 23:29:38

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
Data entry locked.	System	11 Sep 2020 20:30:19
User entered 'Day 6'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:04:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-16T18:10:29', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'e94ccee-ab23-4c22-93c7-cedd10423d9e' User entered 'None (1)'	System	16 Sep 2020 23:10:49
	System	16 Sep 2020 23:10:49



US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:04:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-16T18:10:36', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'e94ccee-ab23-4c22-93c7-cedd10423d9e' User entered 'No (N)'	System	16 Sep 2020 23:10:49
	System	16 Sep 2020 23:10:49

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-16T18:10:39', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'e94ccee-ab23-4c22-93c7-cedd10423d9e' User entered 'No (N)'	System	16 Sep 2020 23:10:49
	System	16 Sep 2020 23:10:49

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:04:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-16T18:10:43', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'e94ccee-ab23-4c22-93c7-cedd10423d9e' User entered 'None (1)'	System	16 Sep 2020 23:10:49
	System	16 Sep 2020 23:10:49

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:04:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-16T18:10:46', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'e94ccee-ab23-4c22-93c7-cedd10423d9e' User entered '16 Sep 2020 18:10'	System	16 Sep 2020 23:10:49
	System	16 Sep 2020 23:10:49

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
Data entry locked.	System	11 Sep 2020 20:30:19
User entered 'Day 7'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:04:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-17T17:37:50', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '0a3c9f1b-e2ff-4ea9-be1e-fa33cd2e7fe7'	System	17 Sep 2020 22:38:18
User entered 'None (1)'	System	17 Sep 2020 22:38:18



US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:04:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-17T17:37:54', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '0a3c9f1b-e2ff-4ea9-be1e-fa33cd2e7fe7'	System	17 Sep 2020 22:38:18
User entered 'No (N)'	System	17 Sep 2020 22:38:18

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-17T17:38:10', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '0a3c9f1b-e2ff-4ea9-be1e-fa33cd2e7fe7'	System	17 Sep 2020 22:38:18
User entered 'No (N)'	System	17 Sep 2020 22:38:18

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:04:53

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-17T17:38:14', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '0a3c9f1b-e2ff-4ea9-be1e-fa33cd2e7fe7'	System	17 Sep 2020 22:38:18
User entered 'None (1)'	System	17 Sep 2020 22:38:18

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:04:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-17T17:38:17', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '0a3c9f1b-e2ff-4ea9-be1e-fa33cd2e7fe7'	System	17 Sep 2020 22:38:18
User entered '17 Sep 2020 17:38'	System	17 Sep 2020 22:38:18

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
Data entry locked.	System	11 Sep 2020 20:30:19
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-11T15:38:12', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '098505c1-5500-48ae-b341-49b10d247279' User entered 'None (0)'	System	11 Sep 2020 20:38:36
	System	11 Sep 2020 20:38:36



US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-11T15:38:15', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '098505c1-5500-48ae-b341-49b10d247279' User entered 'None (0)'	System	11 Sep 2020 20:38:36
	System	11 Sep 2020 20:38:36

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-11T15:38:18', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '098505c1-5500-48ae-b341-49b10d247279' User entered 'None (0)'	System	11 Sep 2020 20:38:36
	System	11 Sep 2020 20:38:36

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-11T15:38:21', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '098505c1-5500-48ae-b341-49b10d247279' User entered 'None (0)'	System	11 Sep 2020 20:38:36
	System	11 Sep 2020 20:38:36

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-11T15:38:24', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '098505c1-5500-48ae-b341-49b10d247279' User entered 'None (0)'	System	11 Sep 2020 20:38:36
	System	11 Sep 2020 20:38:36

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-11T15:38:26', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '098505c1-5500-48ae-b341-49b10d247279' User entered 'None (0)'	System	11 Sep 2020 20:38:36
	System	11 Sep 2020 20:38:36

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-11T15:38:29', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '098505c1-5500-48ae-b341-49b10d247279'	System	11 Sep 2020 20:38:36
User entered 'No (N)'	System	11 Sep 2020 20:38:36

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-11T15:38:32', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '098505c1-5500-48ae-b341-49b10d247279'	System	11 Sep 2020 20:38:36
User entered '11 Sep 2020 15:38'	System	11 Sep 2020 20:38:36

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '11 Sep 2020 15:26'	System	11 Sep 2020 20:30:19



US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '11 Sep 2020 17:56'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
Data entry locked.	System	11 Sep 2020 20:30:19
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-11T20:14:51', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '95583d8a-aa45-4bfc-bc03-1ecf4e1cd797'	System	12 Sep 2020 01:15:13
User entered 'None (0)'	System	12 Sep 2020 01:15:13

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-11T20:14:54', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '95583d8a-aa45-4bfc-bc03-1ecf4e1cd797'	System	12 Sep 2020 01:15:13
User entered 'None (0)'	System	12 Sep 2020 01:15:13

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-11T20:14:57', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '95583d8a-aa45-4bfc-bc03-1ecf4e1cd797'	System	12 Sep 2020 01:15:13
User entered 'None (0)'	System	12 Sep 2020 01:15:13

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-11T20:14:59', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '95583d8a-aa45-4bfc-bc03-1ecf4e1cd797' User entered 'None (0)'	System	12 Sep 2020 01:15:13
	System	12 Sep 2020 01:15:13

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-11T20:15:01', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '95583d8a-aa45-4bfc-bc03-1ecf4e1cd797'	System	12 Sep 2020 01:15:13
User entered 'None (0)'	System	12 Sep 2020 01:15:13

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-11T20:15:03', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '95583d8a-aa45-4bfc-bc03-1ecf4e1cd797'	System	12 Sep 2020 01:15:13
User entered 'None (0)'	System	12 Sep 2020 01:15:13



US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-11T20:15:07', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '95583d8a-aa45-4bfc-bc03-1ecf4e1cd797'	System	12 Sep 2020 01:15:13
User entered 'No (N)'	System	12 Sep 2020 01:15:13

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-11T20:15:10', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '95583d8a-aa45-4bfc-bc03-1ecf4e1cd797'	System	12 Sep 2020 01:15:13
User entered '11 Sep 2020 20:15'	System	12 Sep 2020 01:15:13

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '11 Sep 2020 18:51'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
Data entry locked.	System	11 Sep 2020 20:30:19
User entered 'Day 2'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:04:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-12T16:16:23', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '3143541b-7a61-4297-97d8-c6bfe70dd4f7' User entered 'None (0)'	System	12 Sep 2020 21:16:34
	System	12 Sep 2020 21:16:34

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:04:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-12T16:16:18', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '3143541b-7a61-4297-97d8-c6bfe70dd4f7' User entered 'None (0)'	System	12 Sep 2020 21:16:34
	System	12 Sep 2020 21:16:34

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:04:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-12T16:16:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '3143541b-7a61-4297-97d8-c6bfe70dd4f7' User entered 'None (0)'	System	12 Sep 2020 21:16:34
	System	12 Sep 2020 21:16:34



US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:04:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-12T16:16:03', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '3143541b-7a61-4297-97d8-c6bfe70dd4f7' User entered 'None (0)'	System	12 Sep 2020 21:16:34
	System	12 Sep 2020 21:16:34

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:04:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-12T16:16:05', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '3143541b-7a61-4297-97d8-c6bfe70dd4f7' User entered 'None (0)'	System	12 Sep 2020 21:16:34
	System	12 Sep 2020 21:16:34

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:04:53

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-12T16:16:07', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '3143541b-7a61-4297-97d8-c6bfe70dd4f7' User entered 'None (0)'	System	12 Sep 2020 21:16:34
	System	12 Sep 2020 21:16:34

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-12T16:16:10', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '3143541b-7a61-4297-97d8-c6bfe70dd4f7'	System	12 Sep 2020 21:16:34
User entered 'No (N)'	System	12 Sep 2020 21:16:34

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:04:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-12T16:16:29', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '3143541b-7a61-4297-97d8-c6bfe70dd4f7'	System	12 Sep 2020 21:16:34
User entered '12 Sep 2020 16:16'	System	12 Sep 2020 21:16:34

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
Data entry locked.	System	11 Sep 2020 20:30:19
User entered 'Day 3'	System	11 Sep 2020 20:30:19



US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:04:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-13T12:02:39', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '6aba0444-91de-48d2-82b4-697022abccf4' User entered 'None (0)'	System	13 Sep 2020 17:03:26
	System	13 Sep 2020 17:03:26

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:04:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-13T12:02:42', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '6aba0444-91de-48d2-82b4-697022abccf4' User entered 'None (0)'	System	13 Sep 2020 17:03:26
	System	13 Sep 2020 17:03:26

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:04:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-13T12:02:45', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '6aba0444-91de-48d2-82b4-697022abccf4' User entered 'None (0)'	System	13 Sep 2020 17:03:26
	System	13 Sep 2020 17:03:26

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:04:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-13T12:02:48', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '6aba0444-91de-48d2-82b4-697022abccf4' User entered 'None (0)'	System	13 Sep 2020 17:03:26
	System	13 Sep 2020 17:03:26

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:04:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-13T12:02:50', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '6aba0444-91de-48d2-82b4-697022abccf4' User entered 'None (0)'	System	13 Sep 2020 17:03:26
	System	13 Sep 2020 17:03:26

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:04:53

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-13T12:02:53', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '6aba0444-91de-48d2-82b4-697022abccf4' User entered 'None (0)'	System	13 Sep 2020 17:03:26
	System	13 Sep 2020 17:03:26

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-13T12:02:55', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '6aba0444-91de-48d2-82b4-697022abccf4' User entered 'No (N)'	System	13 Sep 2020 17:03:26
	System	13 Sep 2020 17:03:26

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:04:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-13T12:02:58', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '6aba0444-91de-48d2-82b4-697022abccf4' User entered '13 Sep 2020 12:02'	System	13 Sep 2020 17:03:26
	System	13 Sep 2020 17:03:26



US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
Data entry locked.	System	11 Sep 2020 20:30:19
User entered 'Day 4'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:04:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-14T16:34:41', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'e69426f7-7804-4a85-9234-b6c786eaa0e6'	System	14 Sep 2020 21:35:15
User entered 'None (0)'	System	14 Sep 2020 21:35:15

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:04:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-14T16:34:44', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'e69426f7-7804-4a85-9234-b6c786eaa0e6' User entered 'None (0)'	System	14 Sep 2020 21:35:15
	System	14 Sep 2020 21:35:15

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:04:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-14T16:34:46', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'e69426f7-7804-4a85-9234-b6c786eaa0e6' User entered 'None (0)'	System	14 Sep 2020 21:35:15
	System	14 Sep 2020 21:35:15

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:04:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-14T16:34:50', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'e69426f7-7804-4a85-9234-b6c786eaa0e6' User entered 'None (0)'	System	14 Sep 2020 21:35:15
	System	14 Sep 2020 21:35:15

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:04:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-14T16:34:55', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'e69426f7-7804-4a85-9234-b6c786eaa0e6' User entered 'None (0)'	System	14 Sep 2020 21:35:15
	System	14 Sep 2020 21:35:15



US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:04:53

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-14T16:35:03', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'e69426f7-7804-4a85-9234-b6c786eaa0e6' User entered 'None (0)'	System	14 Sep 2020 21:35:15
	System	14 Sep 2020 21:35:15

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-14T16:35:08', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'e69426f7-7804-4a85-9234-b6c786eaa0e6' User entered 'No (N)'	System	14 Sep 2020 21:35:15
	System	14 Sep 2020 21:35:15

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:04:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-14T16:35:13', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'e69426f7-7804-4a85-9234-b6c786eaa0e6' User entered '14 Sep 2020 16:35'	System	14 Sep 2020 21:35:15
	System	14 Sep 2020 21:35:15

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
Data entry locked.	System	11 Sep 2020 20:30:19
User entered 'Day 5'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:04:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-15T18:28:56', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'd199acfa-b88a-41e0-803c-a6a9cbc7b05e' User entered 'None (0)'	System	15 Sep 2020 23:29:19
	System	15 Sep 2020 23:29:19

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:04:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-15T18:28:58', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'd199acfa-b88a-41e0-803c-a6a9cbc7b05e' User entered 'None (0)'	System	15 Sep 2020 23:29:19
	System	15 Sep 2020 23:29:19



US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:04:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-15T18:29:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'd199acfa-b88a-41e0-803c-a6a9cbc7b05e' User entered 'None (0)'	System	15 Sep 2020 23:29:19
	System	15 Sep 2020 23:29:19

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:04:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-15T18:29:03', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'd199acfa-b88a-41e0-803c-a6a9cbc7b05e' User entered 'None (0)'	System	15 Sep 2020 23:29:19
	System	15 Sep 2020 23:29:19

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:04:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-15T18:29:05', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'd199acfa-b88a-41e0-803c-a6a9cbc7b05e' User entered 'None (0)'	System	15 Sep 2020 23:29:19
	System	15 Sep 2020 23:29:19

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:04:53

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-15T18:29:08', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'd199acfa-b88a-41e0-803c-a6a9cbc7b05e' User entered 'None (0)'	System	15 Sep 2020 23:29:19
	System	15 Sep 2020 23:29:19

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-15T18:29:12', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'd199acfa-b88a-41e0-803c-a6a9cbc7b05e' User entered 'No (N)'	System	15 Sep 2020 23:29:19
	System	15 Sep 2020 23:29:19

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:04:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-15T18:29:15', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'd199acfa-b88a-41e0-803c-a6a9cbc7b05e' User entered '15 Sep 2020 18:29'	System	15 Sep 2020 23:29:19
	System	15 Sep 2020 23:29:19

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 20:30:19



US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
Data entry locked.	System	11 Sep 2020 20:30:19
User entered 'Day 6'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:04:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-16T18:09:59', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'f5029b53-faeb-4f39-add6-4084e43d91d9' User entered 'None (0)'	System	16 Sep 2020 23:10:26
	System	16 Sep 2020 23:10:26

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:04:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-16T18:10:01', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'f5029b53-faeb-4f39-add6-4084e43d91d9' User entered 'None (0)'	System	16 Sep 2020 23:10:26
	System	16 Sep 2020 23:10:26

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:04:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-16T18:10:05', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'f5029b53-faeb-4f39-add6-4084e43d91d9' User entered 'None (0)'	System	16 Sep 2020 23:10:26
	System	16 Sep 2020 23:10:26

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:04:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-16T18:10:09', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'f5029b53-faeb-4f39-add6-4084e43d91d9' User entered 'None (0)'	System	16 Sep 2020 23:10:26
	System	16 Sep 2020 23:10:26

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:04:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-16T18:10:13', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'f5029b53-faeb-4f39-add6-4084e43d91d9' User entered 'None (0)'	System	16 Sep 2020 23:10:26
	System	16 Sep 2020 23:10:26

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:04:53

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-16T18:10:15', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'f5029b53-faeb-4f39-add6-4084e43d91d9' User entered 'None (0)'	System	16 Sep 2020 23:10:26
	System	16 Sep 2020 23:10:26

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-16T18:10:21', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'f5029b53-faeb-4f39-add6-4084e43d91d9' User entered 'No (N)'	System	16 Sep 2020 23:10:26
	System	16 Sep 2020 23:10:26



US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:04:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-16T18:10:24', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'f5029b53-faeb-4f39-add6-4084e43d91d9' User entered '16 Sep 2020 18:10'	System	16 Sep 2020 23:10:26
	System	16 Sep 2020 23:10:26

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
Data entry locked.	System	11 Sep 2020 20:30:19
User entered 'Day 7'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:04:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-17T17:36:50', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '9e9b921d-b0e0-49ca-a859-e69eac162b65' User entered 'None (0)'	System	17 Sep 2020 22:37:17
	System	17 Sep 2020 22:37:17

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:04:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-17T17:36:53', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '9e9b921d-b0e0-49ca-a859-e69eac162b65' User entered 'None (0)'	System	17 Sep 2020 22:37:17
	System	17 Sep 2020 22:37:17

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:04:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-17T17:36:55', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '9e9b921d-b0e0-49ca-a859-e69eac162b65' User entered 'None (0)'	System	17 Sep 2020 22:37:17
	System	17 Sep 2020 22:37:17

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:04:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-17T17:36:58', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '9e9b921d-b0e0-49ca-a859-e69eac162b65' User entered 'None (0)'	System	17 Sep 2020 22:37:17
	System	17 Sep 2020 22:37:17



US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:04:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-17T17:37:01', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '9e9b921d-b0e0-49ca-a859-e69eac162b65' User entered 'None (0)'	System	17 Sep 2020 22:37:17
	System	17 Sep 2020 22:37:17

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:04:53

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-17T17:37:04', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '9e9b921d-b0e0-49ca-a859-e69eac162b65' User entered 'None (0)'	System	17 Sep 2020 22:37:17
	System	17 Sep 2020 22:37:17

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-17T17:37:11', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '9e9b921d-b0e0-49ca-a859-e69eac162b65' User entered 'No (N)'	System	17 Sep 2020 22:37:17
	System	17 Sep 2020 22:37:17

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:04:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-09-17T17:37:15', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '9e9b921d-b0e0-49ca-a859-e69eac162b65' User entered '17 Sep 2020 17:37'	System	17 Sep 2020 22:37:17
	System	17 Sep 2020 22:37:17

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 20:30:19

US3852177

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 20:30:19

US3852177

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:55:17
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	18 Sep 2020 20:20:15

US3852177

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:55:20
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '18 Sep 2020'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	18 Sep 2020 20:20:15



US3852177

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:55:22
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	18 Sep 2020 20:20:15

US3852177

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:55:24
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	18 Sep 2020 20:20:15

US3852177

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:55:31
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	18 Sep 2020 20:20:19

US3852177

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
User entered 'I'	System	18 Sep 2020 20:20:19

US3852177

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:00:14
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	Jessica Mcdowell (b) (4)	25 Sep 2020 15:15:20

US3852177

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:00:15
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '25 Sep 2020'	(b) (4) Jessica McDowell (b) (4)	25 Sep 2020 15:15:20
	(b) (4)	

US3852177

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:00:17
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Jessica McDowell (b) (4) (b) (4)	25 Sep 2020 15:15:20

US3852177

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:00:18
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	Jessica McDowell (b) (4)	25 Sep 2020 15:15:20



US3852177

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:00:37
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	02 Oct 2020 18:29:46

US3852177

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
User entered 'I'	System	02 Oct 2020 18:29:46

US3852177

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:57:02
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	02 Oct 2020 18:29:57

US3852177

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:57:04
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '2 Oct 2020'	(b) (4) Martha Bunnell-Pollak (b) (4)	02 Oct 2020 18:29:57

US3852177

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:57:05
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Martha Bunnell-Pollak (b) (4)	02 Oct 2020 18:29:57

US3852177

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:57:07
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	02 Oct 2020 18:29:57

US3852177

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:57:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	02 Oct 2020 18:30:02

US3852177

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:22:12
User entered 'I'	System	02 Oct 2020 18:30:02



US3852177

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:57:57
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 19:28:43

US3852177

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:57:59
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '6 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 19:28:43

US3852177

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:58:01
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	06 Oct 2020 19:28:43

**US3852177**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:04:53**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
User entered 'VISIT2'	System	06 Oct 2020 19:28:43

US3852177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	08 Oct 2020 16:18:20

US3852177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:58:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 16:18:20

US3852177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:58:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '6 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 16:18:20

US3852177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:58:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '13:43'	(b) (4), (b) (6)	08 Oct 2020 16:18:20



US3852177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:53

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
User entered '6 Oct 2020 13:43'	System	08 Oct 2020 16:18:20

US3852177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:58:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '98.9' F	(b) (4), (b) (6)	08 Oct 2020 16:18:20

US3852177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:58:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Other (Other)'	(b) (4), (b) (6)	08 Oct 2020 16:18:20

US3852177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:58:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Infrared/forehead'	(b) (4), (b) (6)	08 Oct 2020 16:18:20

US3852177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:58:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '80'	(b) (4), (b) (6)	08 Oct 2020 16:18:20

US3852177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
User entered 'bpm'	System	08 Oct 2020 16:18:20

US3852177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:58:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '18'	(b) (4), (b) (6)	08 Oct 2020 16:18:20

US3852177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
User entered 'breaths/min'	System	08 Oct 2020 16:18:20



US3852177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:58:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '125'	(b) (4), (b) (6)	08 Oct 2020 16:18:20

US3852177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
User entered 'mmHg'	System	08 Oct 2020 16:18:20

US3852177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:58:16
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '79'	(b) (4), (b) (6)	08 Oct 2020 16:18:20

US3852177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:04:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
User entered 'mmHg'	System	08 Oct 2020 16:18:20

US3852177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:53

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	08 Oct 2020 16:18:20

US3852177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:58:39
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 16:18:20

US3852177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:58:39
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '6 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 16:18:20

US3852177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:58:39
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '14:32'	(b) (4), (b) (6)	08 Oct 2020 16:18:20



US3852177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
User entered '6 Oct 2020 14:32'	System	08 Oct 2020 16:18:20

US3852177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:58:39
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '98.7' F	(b) (4), (b) (6)	08 Oct 2020 16:18:20

US3852177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:58:39
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Other (Other)'	(b) (4), (b) (6)	08 Oct 2020 16:18:20

US3852177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:58:39
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Infrared/forehead'	(b) (4), (b) (6)	08 Oct 2020 16:18:20

US3852177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:58:39
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '84'	(b) (4), (b) (6)	08 Oct 2020 16:18:20

US3852177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
User entered 'bpm'	System	08 Oct 2020 16:18:20

US3852177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:58:39
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '18'	(b) (4), (b) (6)	08 Oct 2020 16:18:20

US3852177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
User entered 'breaths/min'	System	08 Oct 2020 16:18:20



US3852177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:58:39
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '135'	(b) (4), (b) (6)	08 Oct 2020 16:18:20

US3852177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
User entered 'mmHg'	System	08 Oct 2020 16:18:20

US3852177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:58:39
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '77'	(b) (4), (b) (6)	08 Oct 2020 16:18:20

US3852177

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:04:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
User entered 'mmHg'	System	08 Oct 2020 16:18:20

US3852177

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:58:51
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	(b) (4), (b) (6)	08 Oct 2020 16:18:59

US3852177

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:58:53
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 16:18:59

US3852177

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:53

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:59:32
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 19:29:15

US3852177

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:53

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:59:34
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 19:29:15



US3852177

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:53

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:59:35
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 19:29:15

US3852177

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:53

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
User entered 'MRNA-1273 OR PLACEBO'	System	06 Oct 2020 19:29:15

US3852177

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:53

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:59:38
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '6 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 19:29:15

US3852177

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:53

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:59:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '14:01'	(b) (4), (b) (6)	06 Oct 2020 19:29:15

US3852177

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:53

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
User entered '6 Oct 2020 14:01'	System	06 Oct 2020 19:29:15

US3852177

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:53

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:59:46
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	06 Oct 2020 19:29:15

US3852177

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:53

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 03:59:49
User entered 'ONCE'	System	06 Oct 2020 19:29:15

US3852177

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:04:53

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
User entered 'INTRAMUSCULAR'	System	06 Oct 2020 19:29:15



US3852177

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:00:13
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 16:19:57

US3852177

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:00:15
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '6 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 16:19:57

US3852177

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:00:17
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '14:00'	(b) (4), (b) (6)	08 Oct 2020 16:19:57

US3852177

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
User entered '6 Oct 2020 14:00'	System	08 Oct 2020 16:19:57

US3852177

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:04:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:00:41
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '6 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 16:20:21

US3852177

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:04:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	08 Oct 2020 16:20:21

US3852177

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:04:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:00:30
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 16:20:21

US3852177

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:04:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:00:30
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '13:45'	(b) (4), (b) (6)	08 Oct 2020 16:20:21



US3852177

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:04:53

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
User entered '6 Oct 2020 13:45'	System	08 Oct 2020 16:20:21

US3852177

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:04:53

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	08 Oct 2020 16:20:21

US3852177

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:04:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:00:50
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	(b) (4), (b) (6)	08 Oct 2020 16:20:21

US3852177

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:04:53

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:00:50
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 16:20:21

US3852177

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:04:53

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
User entered empty.	System	08 Oct 2020 16:20:21

US3852177

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 04:35:26
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 19:29:23

US3852177

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
User entered 'I'	System	06 Oct 2020 19:29:23

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
Data entry locked.	System	06 Oct 2020 19:29:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 19:29:15



US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-06T14:33:32', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '6062c347-1d39-440d-a116-35e3ab3e5792'	System	06 Oct 2020 19:35:41
User entered 'Yes (Y)'	System	06 Oct 2020 19:35:41

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-06T14:33:36', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '6062c347-1d39-440d-a116-35e3ab3e5792' User entered '98.7'	System	06 Oct 2020 19:35:41
	System	06 Oct 2020 19:35:41

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-06T14:33:41', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '6062c347-1d39-440d-a116-35e3ab3e5792'	System	06 Oct 2020 19:35:41
User entered 'No (N)'	System	06 Oct 2020 19:35:41

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-06T14:33:46', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '6062c347-1d39-440d-a116-35e3ab3e5792' User entered '06 Oct 2020 14:33'	System	06 Oct 2020 19:35:41
	System	06 Oct 2020 19:35:41

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
User entered '06 Oct 2020 14:21'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
User entered '06 Oct 2020 16:51'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
Data entry locked.	System	06 Oct 2020 19:29:15
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:19:55



US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:19:55

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:19:55

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:19:55

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:19:55

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:19:55

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
User entered '06 Oct 2020 17:46'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
Data entry locked.	System	06 Oct 2020 19:29:15
User entered 'Day 2'	System	06 Oct 2020 19:29:15



US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:04:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-07T12:03:14', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '9c9f553b-4216-4ff6-a445-6e6815f96ea5' User entered 'Yes (Y)'	System	07 Oct 2020 17:03:28
	System	07 Oct 2020 17:03:28

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:04:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-07T12:03:19', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '9c9f553b-4216-4ff6-a445-6e6815f96ea5' User entered '98.7'	System	07 Oct 2020 17:03:28
	System	07 Oct 2020 17:03:28

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:04:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-07T12:03:23', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '9c9f553b-4216-4ff6-a445-6e6815f96ea5' User entered 'No (N)'	System	07 Oct 2020 17:03:28
	System	07 Oct 2020 17:03:28

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:04:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-07T12:03:26', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '9c9f553b-4216-4ff6-a445-6e6815f96ea5' User entered '07 Oct 2020 12:03'	System	07 Oct 2020 17:03:28
	System	07 Oct 2020 17:03:28

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
Data entry locked.	System	06 Oct 2020 19:29:15
User entered 'Day 3'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:04:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:19:55



US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:04:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:19:55

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:04:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:04:53

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:19:55

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:04:53

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:19:55

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:04:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:19:55

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
Data entry locked.	System	06 Oct 2020 19:29:15
User entered 'Day 4'	System	06 Oct 2020 19:29:15



US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:04:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:19:55

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:04:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:19:55

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:04:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:04:53

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:19:55

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:04:53

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:19:55

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:04:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:19:55

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 19:29:15



US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
Data entry locked.	System	06 Oct 2020 19:29:15
User entered 'Day 5'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:04:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-11T09:34:43', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '71fed89b-376f-4126-89f5-cb8866486da6' User entered 'Yes (Y)'	System	11 Oct 2020 14:34:56
	System	11 Oct 2020 14:34:56

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:04:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-11T09:34:48', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '71fed89b-376f-4126-89f5-cb8866486da6'	System	11 Oct 2020 14:34:56
User entered '98.5'	System	11 Oct 2020 14:34:56

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:04:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-11T09:34:52', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '71fed89b-376f-4126-89f5-cb8866486da6'	System	11 Oct 2020 14:34:56
User entered 'No (N)'	System	11 Oct 2020 14:34:56

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:04:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-11T09:34:55', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '71fed89b-376f-4126-89f5-cb8866486da6' User entered '11 Oct 2020 09:34'	System	11 Oct 2020 14:34:56
	System	11 Oct 2020 14:34:56

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
Data entry locked.	System	06 Oct 2020 19:29:15
User entered 'Day 6'	System	06 Oct 2020 19:29:15



US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:04:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-11T12:36:47', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'b93539ad-6998-4126-a0a7-5f6fec90e1'	System	11 Oct 2020 17:37:21
User entered 'Yes (Y)'	System	11 Oct 2020 17:37:21

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:04:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-11T12:37:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'b93539ad-6998-4126-a0a7-5f6fec90ecec1' User entered '97.8'	System	11 Oct 2020 17:37:21
	System	11 Oct 2020 17:37:21

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:04:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-11T12:37:13', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'b93539ad-6998-4126-a0a7-5f6fec90ecec1' User entered 'No (N)'	System	11 Oct 2020 17:37:21
	System	11 Oct 2020 17:37:21

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:04:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-11T12:37:19', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'b93539ad-6998-4126-a0a7-5f6fec90ecec1' User entered '11 Oct 2020 12:37'	System	11 Oct 2020 17:37:21
	System	11 Oct 2020 17:37:21

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
Data entry locked.	System	06 Oct 2020 19:29:15
User entered 'Day 7'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:04:53

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-13T06:37:54', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '0f9e92d7-0da8-489f-b37a-59879f52847c' User entered 'Yes (Y)'	System	13 Oct 2020 11:38:12
	System	13 Oct 2020 11:38:12



US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:04:53

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-13T06:38:01', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '0f9e92d7-0da8-489f-b37a-59879f52847c' User entered '97.6'	System	13 Oct 2020 11:38:12
	System	13 Oct 2020 11:38:12

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:04:53

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-13T06:38:06', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '0f9e92d7-0da8-489f-b37a-59879f52847c' User entered 'No (N)'	System	13 Oct 2020 11:38:12
	System	13 Oct 2020 11:38:12

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:04:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-13T06:38:09', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '0f9e92d7-0da8-489f-b37a-59879f52847c' User entered '13 Oct 2020 06:38'	System	13 Oct 2020 11:38:12
	System	13 Oct 2020 11:38:12

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:19:55
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
Data entry locked.	System	06 Oct 2020 19:29:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-06T14:33:51', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '7c0a2f93-d335-4847-9bfc-7a95a5768747'	System	06 Oct 2020 19:35:52
User entered 'None (1)'	System	06 Oct 2020 19:35:52

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-06T14:33:56', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '7c0a2f93-d335-4847-9bfc-7a95a5768747'	System	06 Oct 2020 19:35:52
User entered 'No (N)'	System	06 Oct 2020 19:35:52



US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-06T14:33:59', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '7c0a2f93-d335-4847-9bfc-7a95a5768747'	System	06 Oct 2020 19:35:52
User entered 'No (N)'	System	06 Oct 2020 19:35:52

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-06T14:34:03', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '7c0a2f93-d335-4847-9bfc-7a95a5768747'	System	06 Oct 2020 19:35:52
User entered 'None (1)'	System	06 Oct 2020 19:35:52

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-06T14:34:06', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '7c0a2f93-d335-4847-9bfc-7a95a5768747' User entered '06 Oct 2020 14:34'	System	06 Oct 2020 19:35:52
	System	06 Oct 2020 19:35:52

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '06 Oct 2020 14:21'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '06 Oct 2020 16:51'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
Data entry locked.	System	06 Oct 2020 19:29:15
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48



US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '06 Oct 2020 17:46'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
Data entry locked.	System	06 Oct 2020 19:29:15
User entered 'Day 2'	System	06 Oct 2020 19:29:15



US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:04:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-07T12:02:18', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '0b8b97f2-240d-4e99-8af1-e027a8dd96f9'	System	07 Oct 2020 17:03:14
User entered 'Does not interfere with activity (2)'	System	07 Oct 2020 17:03:14

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:04:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-07T12:02:30', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '0b8b97f2-240d-4e99-8af1-e027a8dd96f9' User entered 'No (N)'	System	07 Oct 2020 17:03:14
	System	07 Oct 2020 17:03:14

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:04:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-07T12:02:33', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '0b8b97f2-240d-4e99-8af1-e027a8dd96f9' User entered 'Yes (Y)'	System	07 Oct 2020 17:03:14
	System	07 Oct 2020 17:03:14

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:04:53

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-07T12:02:48', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '0b8b97f2-240d-4e99-8af1-e027a8dd96f9' User entered '3'	System	07 Oct 2020 17:03:14
	System	07 Oct 2020 17:03:14

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:04:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-07T12:02:55', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '0b8b97f2-240d-4e99-8af1-e027a8dd96f9'	System	07 Oct 2020 17:03:14
User entered 'None (1)'	System	07 Oct 2020 17:03:14

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:04:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-07T12:02:59', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '0b8b97f2-240d-4e99-8af1-e027a8dd96f9' User entered '07 Oct 2020 12:02'	System	07 Oct 2020 17:03:14
	System	07 Oct 2020 17:03:14

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 19:29:15



US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
Data entry locked.	System	06 Oct 2020 19:29:15
User entered 'Day 3'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:04:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:04:53

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:04:53

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:04:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:04:53

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:04:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:04:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48



US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
Data entry locked.	System	06 Oct 2020 19:29:15
User entered 'Day 4'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:04:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:04:53

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:04:53

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:04:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:04:53

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48



US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:04:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:04:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
Data entry locked.	System	06 Oct 2020 19:29:15
User entered 'Day 5'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:04:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-11T09:35:02', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'efa4fa0e-2d0a-4509-9120-d598ddb4f57c'	System	11 Oct 2020 14:35:19
User entered 'None (1)'	System	11 Oct 2020 14:35:19

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:04:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-11T09:35:09', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'efa4fa0e-2d0a-4509-9120-d598ddb4f57c' User entered 'No (N)'	System	11 Oct 2020 14:35:19
	System	11 Oct 2020 14:35:19

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:04:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-11T09:35:11', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'efa4fa0e-2d0a-4509-9120-d598ddb4f57c'	System	11 Oct 2020 14:35:19
User entered 'No (N)'	System	11 Oct 2020 14:35:19



US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:04:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-11T09:35:14', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'efa4fa0e-2d0a-4509-9120-d598ddb4f57c'	System	11 Oct 2020 14:35:19
User entered 'None (1)'	System	11 Oct 2020 14:35:19

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:04:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-11T09:35:16', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'efa4fa0e-2d0a-4509-9120-d598ddb4f57c' User entered '11 Oct 2020 09:35'	System	11 Oct 2020 14:35:19
	System	11 Oct 2020 14:35:19

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
Data entry locked.	System	06 Oct 2020 19:29:15
User entered 'Day 6'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:04:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-11T12:38:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '3152f20b-6ddb-487a-aef6-36776c581f56'	System	11 Oct 2020 17:38:24
User entered 'None (1)'	System	11 Oct 2020 17:38:24

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:04:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-11T12:38:14', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '3152f20b-6ddb-487a-aef6-36776c581f56' User entered 'No (N)'	System	11 Oct 2020 17:38:24
	System	11 Oct 2020 17:38:24

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:04:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-11T12:38:17', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '3152f20b-6ddb-487a-aef6-36776c581f56'	System	11 Oct 2020 17:38:24
User entered 'No (N)'	System	11 Oct 2020 17:38:24



US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:04:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-11T12:38:20', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '3152f20b-6ddb-487a-aef6-36776c581f56'	System	11 Oct 2020 17:38:24
User entered 'None (1)'	System	11 Oct 2020 17:38:24

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:04:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-11T12:38:22', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '3152f20b-6ddb-487a-aef6-36776c581f56'	System	11 Oct 2020 17:38:24
User entered '11 Oct 2020 12:38'	System	11 Oct 2020 17:38:24

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
Data entry locked.	System	06 Oct 2020 19:29:15
User entered 'Day 7'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:04:53

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-13T06:37:33', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '7adc58c6-2dbf-48f2-aef9-3bd974d083c4' User entered 'None (1)'	System	13 Oct 2020 11:37:51
	System	13 Oct 2020 11:37:51

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:04:53

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-13T06:37:36', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '7adc58c6-2dbf-48f2-aef9-3bd974d083c4'	System	13 Oct 2020 11:37:51
User entered 'No (N)'	System	13 Oct 2020 11:37:51

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:04:53

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-13T06:37:40', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '7adc58c6-2dbf-48f2-aef9-3bd974d083c4'	System	13 Oct 2020 11:37:51
User entered 'No (N)'	System	13 Oct 2020 11:37:51



US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:04:53

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-13T06:37:46', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '7adc58c6-2dbf-48f2-aef9-3bd974d083c4'	System	13 Oct 2020 11:37:51
User entered 'None (1)'	System	13 Oct 2020 11:37:51

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:04:53

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-13T06:37:49', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '7adc58c6-2dbf-48f2-aef9-3bd974d083c4' User entered '13 Oct 2020 06:37'	System	13 Oct 2020 11:37:51
	System	13 Oct 2020 11:37:51

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
Data entry locked.	System	06 Oct 2020 19:29:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-06T14:33:02', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '5adea971-9fe9-4180-bd41-a935d7c0a922'	System	06 Oct 2020 19:35:30
User entered 'None (0)'	System	06 Oct 2020 19:35:30

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-06T14:33:05', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '5adea971-9fe9-4180-bd41-a935d7c0a922'	System	06 Oct 2020 19:35:30
User entered 'None (0)'	System	06 Oct 2020 19:35:30

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-06T14:33:09', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '5adea971-9fe9-4180-bd41-a935d7c0a922'	System	06 Oct 2020 19:35:30
User entered 'None (0)'	System	06 Oct 2020 19:35:30



US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-06T14:33:11', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '5adea971-9fe9-4180-bd41-a935d7c0a922' User entered 'None (0)'	System	06 Oct 2020 19:35:30
	System	06 Oct 2020 19:35:30

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-06T14:33:13', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '5adea971-9fe9-4180-bd41-a935d7c0a922' User entered 'None (0)'	System	06 Oct 2020 19:35:30
	System	06 Oct 2020 19:35:30

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-06T14:33:18', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '5adea971-9fe9-4180-bd41-a935d7c0a922'	System	06 Oct 2020 19:35:30
User entered 'None (0)'	System	06 Oct 2020 19:35:30

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-06T14:33:21', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '5adea971-9fe9-4180-bd41-a935d7c0a922'	System	06 Oct 2020 19:35:30
User entered 'No (N)'	System	06 Oct 2020 19:35:30

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-06T14:33:25', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '5adea971-9fe9-4180-bd41-a935d7c0a922' User entered '06 Oct 2020 14:33'	System	06 Oct 2020 19:35:30
	System	06 Oct 2020 19:35:30

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '06 Oct 2020 14:21'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '06 Oct 2020 16:51'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
Data entry locked.	System	06 Oct 2020 19:29:15
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 19:29:15



US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:17:48



US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '06 Oct 2020 17:46'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
Data entry locked.	System	06 Oct 2020 19:29:15
User entered 'Day 2'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:04:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-07T12:00:46', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'c92a05ac-5a51-4d2e-8db6-d498dfae620b' User entered 'None (0)'	System	07 Oct 2020 17:01:45
	System	07 Oct 2020 17:01:45

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:04:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-07T12:00:49', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'c92a05ac-5a51-4d2e-8db6-d498dfae620b' User entered 'None (0)'	System	07 Oct 2020 17:01:45
	System	07 Oct 2020 17:01:45

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:04:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-07T12:00:54', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'c92a05ac-5a51-4d2e-8db6-d498dfae620b' User entered 'None (0)'	System	07 Oct 2020 17:01:45
	System	07 Oct 2020 17:01:45

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:04:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-07T12:00:57', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'c92a05ac-5a51-4d2e-8db6-d498dfae620b' User entered 'None (0)'	System	07 Oct 2020 17:01:45
	System	07 Oct 2020 17:01:45

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:04:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-07T12:01:01', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'c92a05ac-5a51-4d2e-8db6-d498dfae620b' User entered 'None (0)'	System	07 Oct 2020 17:01:45
	System	07 Oct 2020 17:01:45



US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:04:53

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-07T12:01:03', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'c92a05ac-5a51-4d2e-8db6-d498dfae620b' User entered 'None (0)'	System	07 Oct 2020 17:01:45
	System	07 Oct 2020 17:01:45

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:04:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-07T12:01:08', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'c92a05ac-5a51-4d2e-8db6-d498dfae620b' User entered 'No (N)'	System	07 Oct 2020 17:01:45
	System	07 Oct 2020 17:01:45

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:04:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-07T12:01:11', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'c92a05ac-5a51-4d2e-8db6-d498dfae620b' User entered '07 Oct 2020 12:01'	System	07 Oct 2020 17:01:45
	System	07 Oct 2020 17:01:45

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
Data entry locked.	System	06 Oct 2020 19:29:15
User entered 'Day 3'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:04:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:04:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:17:48



US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:04:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:04:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:04:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:04:53

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:04:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:04:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 19:29:15



US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
Data entry locked.	System	06 Oct 2020 19:29:15
User entered 'Day 4'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:04:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:04:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:04:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:04:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:04:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:04:53

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:04:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48



US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:04:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Feb 2021 10:17:48

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
Data entry locked.	System	06 Oct 2020 19:29:15
User entered 'Day 5'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:04:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-11T09:35:21', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '830b8720-41a4-41d7-8b80-70ebace7c735'	System	11 Oct 2020 14:35:36
User entered 'None (0)'	System	11 Oct 2020 14:35:36

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:04:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-11T09:35:22', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '830b8720-41a4-41d7-8b80-70ebace7c735'	System	11 Oct 2020 14:35:36
User entered 'None (0)'	System	11 Oct 2020 14:35:36

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:04:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-11T09:35:24', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '830b8720-41a4-41d7-8b80-70ebace7c735'	System	11 Oct 2020 14:35:36
User entered 'None (0)'	System	11 Oct 2020 14:35:36

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:04:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-11T09:35:26', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '830b8720-41a4-41d7-8b80-70ebace7c735' User entered 'None (0)'	System	11 Oct 2020 14:35:36
	System	11 Oct 2020 14:35:36



US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:04:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-11T09:35:27', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '830b8720-41a4-41d7-8b80-70ebace7c735' User entered 'None (0)'	System	11 Oct 2020 14:35:36
	System	11 Oct 2020 14:35:36

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:04:53

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-11T09:35:28', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '830b8720-41a4-41d7-8b80-70ebace7c735' User entered 'None (0)'	System	11 Oct 2020 14:35:36
	System	11 Oct 2020 14:35:36

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:04:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-11T09:35:31', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '830b8720-41a4-41d7-8b80-70ebace7c735'	System	11 Oct 2020 14:35:36
User entered 'No (N)'	System	11 Oct 2020 14:35:36

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:04:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-11T09:35:33', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '830b8720-41a4-41d7-8b80-70ebace7c735'	System	11 Oct 2020 14:35:36
User entered '11 Oct 2020 09:35'	System	11 Oct 2020 14:35:36

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
Data entry locked.	System	06 Oct 2020 19:29:15
User entered 'Day 6'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:04:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-11T12:37:33', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'ded8bc47-a7df-4be1-90fd-c6815e4bc4cf' User entered 'None (0)'	System	11 Oct 2020 17:37:53
	System	11 Oct 2020 17:37:53



US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:04:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-11T12:37:36', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'ded8bc47-a7df-4be1-90fd-c6815e4bc4cf' User entered 'None (0)'	System	11 Oct 2020 17:37:53
	System	11 Oct 2020 17:37:53

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:04:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-11T12:37:37', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'ded8bc47-a7df-4be1-90fd-c6815e4bc4cf' User entered 'None (0)'	System	11 Oct 2020 17:37:53
	System	11 Oct 2020 17:37:53

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:04:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-11T12:37:40', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'ded8bc47-a7df-4be1-90fd-c6815e4bc4cf' User entered 'None (0)'	System	11 Oct 2020 17:37:53
	System	11 Oct 2020 17:37:53

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:04:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-11T12:37:42', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'ded8bc47-a7df-4be1-90fd-c6815e4bc4cf' User entered 'None (0)'	System	11 Oct 2020 17:37:53
	System	11 Oct 2020 17:37:53

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:04:53

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-11T12:37:44', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'ded8bc47-a7df-4be1-90fd-c6815e4bc4cf' User entered 'None (0)'	System	11 Oct 2020 17:37:53
	System	11 Oct 2020 17:37:53

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:04:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-11T12:37:47', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'ded8bc47-a7df-4be1-90fd-c6815e4bc4cf' User entered 'No (N)'	System	11 Oct 2020 17:37:53
	System	11 Oct 2020 17:37:53

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:04:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-11T12:37:50', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'ded8bc47-a7df-4be1-90fd-c6815e4bc4cf' User entered '11 Oct 2020 12:37'	System	11 Oct 2020 17:37:53
	System	11 Oct 2020 17:37:53

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 19:29:15



US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
Data entry locked.	System	06 Oct 2020 19:29:15
User entered 'Day 7'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:04:53

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-13T06:37:13', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '17073f0c-3b44-441f-9404-e3c7994dac6b' User entered 'None (0)'	System	13 Oct 2020 11:37:30
	System	13 Oct 2020 11:37:30

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:04:53

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-13T06:37:14', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '17073f0c-3b44-441f-9404-e3c7994dac6b' User entered 'None (0)'	System	13 Oct 2020 11:37:30
	System	13 Oct 2020 11:37:30

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:04:53

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-13T06:37:16', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '17073f0c-3b44-441f-9404-e3c7994dac6b' User entered 'None (0)'	System	13 Oct 2020 11:37:30
	System	13 Oct 2020 11:37:30

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:04:53

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-13T06:37:17', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '17073f0c-3b44-441f-9404-e3c7994dac6b' User entered 'None (0)'	System	13 Oct 2020 11:37:30
	System	13 Oct 2020 11:37:30

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:04:53

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-13T06:37:19', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '17073f0c-3b44-441f-9404-e3c7994dac6b' User entered 'None (0)'	System	13 Oct 2020 11:37:30
	System	13 Oct 2020 11:37:30

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:04:53

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-13T06:37:21', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '17073f0c-3b44-441f-9404-e3c7994dac6b' User entered 'None (0)'	System	13 Oct 2020 11:37:30
	System	13 Oct 2020 11:37:30



US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:04:53

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-13T06:37:23', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '17073f0c-3b44-441f-9404-e3c7994dac6b' User entered 'No (N)'	System	13 Oct 2020 11:37:30
	System	13 Oct 2020 11:37:30

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:04:53

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-10-13T06:37:26', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '17073f0c-3b44-441f-9404-e3c7994dac6b' User entered '13 Oct 2020 06:37'	System	13 Oct 2020 11:37:30
	System	13 Oct 2020 11:37:30

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:04:53

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 19:29:15

US3852177

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:04:53

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:17:48
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 19:29:15

US3852177

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:28:50
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:09:27

US3852177

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:28:52
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 20:09:27

US3852177

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:28:55
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	13 Oct 2020 20:09:27

US3852177

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:28:57
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:09:27



US3852177

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:29:29
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:09:33

US3852177

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
User entered 'I'	System	13 Oct 2020 20:09:33

US3852177

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:03:33
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	20 Oct 2020 22:06:54

US3852177

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:03:34
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '20 Oct 2020'	(b) (4) Martha Bunnell-Pollak (b) (4)	20 Oct 2020 22:06:54

US3852177

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:03:36
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Martha Bunnell-Pollak (b) (4)	20 Oct 2020 22:06:54

US3852177

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:03:38
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	20 Oct 2020 22:06:54

US3852177

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:03:58
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	20 Oct 2020 22:06:57

US3852177

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
User entered 'I'	System	20 Oct 2020 22:06:57



US3852177

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:05:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	27 Oct 2020 15:34:32

US3852177

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:05:08
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '27 Oct 2020'	(b) (4) Martha Bunnell-Pollak (b) (4)	27 Oct 2020 15:34:32

US3852177

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:05:10
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Martha Bunnell-Pollak (b) (4)	27 Oct 2020 15:34:32

US3852177

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:05:12
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	27 Oct 2020 15:34:32

US3852177

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:05:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	27 Oct 2020 15:34:35

US3852177

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
User entered 'I'	System	27 Oct 2020 15:34:35

US3852177

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:33:39
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	Jessica Bartlett (b) (4)	19 Nov 2020 16:28:38

US3852177

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:53

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:33:37
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
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)	24 Nov 2020 20:30:25
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'Correct as entered. Patient is OOW. Sponsor and PI have been informed' (Site from System).	Jessica Bartlett (b) (4)	19 Nov 2020 16:29:01
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	19 Nov 2020 16:28:38
User entered '19 Nov 2020'	Jessica Bartlett (b) (4)	19 Nov 2020 16:28:38



US3852177

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:53

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:33:43
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Clinic (Clinic)'	Jessica Bartlett (b) (4)	19 Nov 2020 16:28:38

**US3852177**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:04:53**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
User entered 'VISIT3'	System	19 Nov 2020 16:28:38

US3852177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:40:17
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	Jessica Bartlett (b) (4)	19 Nov 2020 16:26:17

US3852177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:40:15
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '19 Nov 2020'	Jessica Bartlett (b) (4)	19 Nov 2020 16:26:17

US3852177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:40:10
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '09:56'	Jessica Bartlett (b) (4)	19 Nov 2020 16:26:17

US3852177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
User entered '19 Nov 2020 09:56'	System	19 Nov 2020 16:26:17

US3852177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:40:01
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '97.5' F	Jessica Bartlett (b) (4)	19 Nov 2020 16:26:17

US3852177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:40:26
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Other (Other)'	Jessica Bartlett (b) (4)	19 Nov 2020 16:26:17



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Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:40:30
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'infrared/forehead'	Jessica Bartlett (b) (4)	19 Nov 2020 16:26:17

US3852177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:40:33
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '71'	Jessica Bartlett (b) (4)	19 Nov 2020 16:26:17

US3852177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
User entered 'bpm'	System	19 Nov 2020 16:26:17

US3852177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:40:34
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '18'	Jessica Bartlett (b) (4)	19 Nov 2020 16:26:17

US3852177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
User entered 'breaths/min'	System	19 Nov 2020 16:26:17

US3852177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:40:39
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '133'	Jessica Bartlett (b) (4)	19 Nov 2020 16:26:17

US3852177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
User entered 'mmHg'	System	19 Nov 2020 16:26:17

US3852177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:40:41
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '90'	Jessica Bartlett (b) (4)	19 Nov 2020 16:26:17



US3852177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
User entered 'mmHg'	System	19 Nov 2020 16:26:17

US3852177

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59

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Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59

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Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:41:19
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	Jessica Bartlett (b) (4)	19 Nov 2020 16:29:14

US3852177

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:41:26
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	Jessica Bartlett (b) (4)	19 Nov 2020 16:29:14

US3852177

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:41:00
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	Jessica Bartlett (b) (4)	19 Nov 2020 16:29:29

US3852177

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:53

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:41:02
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '19 Nov 2020'	(b) (4) Jessica Bartlett (b) (4) (b) (4)	19 Nov 2020 16:29:29

US3852177

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:41:03
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '10:15'	(b) (4) Jessica Bartlett (b) (4) (b) (4)	19 Nov 2020 16:29:29



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Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:53

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
User entered '19 Nov 2020 10:15'	System	19 Nov 2020 16:29:29

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Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:42:20
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	Jessica Bartlett (b) (4)	19 Nov 2020 16:29:39

US3852177

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:52:59
User entered 'I'	System	19 Nov 2020 16:29:39

US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00
Data entry locked.	System	11 Sep 2020 20:30:19
User entered 'Day 64'	System	11 Sep 2020 20:30:19

US3852177

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00



US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

Fever (Temperature  $\geq$  100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00



US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00



US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00
Data entry locked.	System	11 Sep 2020 20:30:19
User entered '11 Nov 2020 00:01'	System	11 Sep 2020 20:30:19

**US3852177**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00
Data entry locked.	System	11 Sep 2020 20:30:19
User entered '15 Nov 2020 23:59'	System	11 Sep 2020 20:30:19

US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00
Data entry locked.	System	11 Sep 2020 20:30:19
User entered 'Day 71'	System	11 Sep 2020 20:30:19



US3852177

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

Fever (Temperature  $\geq$  100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00



US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00



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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

US3852177

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00



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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00

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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00
Data entry locked.	System	11 Sep 2020 20:30:19
User entered '18 Nov 2020 00:01'	System	11 Sep 2020 20:30:19

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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:51:00
Data entry locked.	System	11 Sep 2020 20:30:19
User entered '22 Nov 2020 23:59'	System	11 Sep 2020 20:30:19

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 07:51:00

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 07:51:00

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 07:51:00

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-11-29T18:31:25', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '6c0956c3-c26c-40d4-9cf1-61590a80ecf5'	System	30 Nov 2020 00:32:05
User entered 'No (N)'	System	30 Nov 2020 00:32:05



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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

Have you been exposed to someone with 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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-11-29T18:31:34', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '6c0956c3-c26c-40d4-9cf1-61590a80ecf5'	System	30 Nov 2020 00:32:05
User entered 'Yes (Y)'	System	30 Nov 2020 00:32:05

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Please 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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-11-29T18:31:51', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '6c0956c3-c26c-40d4-9cf1-61590a80ecf5'	System	30 Nov 2020 00:32:05
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Nov 2020 00:32:05

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-11-29T18:31:56', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '6c0956c3-c26c-40d4-9cf1-61590a80ecf5'	System	30 Nov 2020 00:32:05
User entered '29 Nov 2020 18:31:56'	System	30 Nov 2020 00:32:05

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 07:51:00

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 07:51:00

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 07:51:00



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 07:51:00

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 07:51:00

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-12-22T12:34:55', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'f04699e9-cee8-4a40-8d37-9121b1ba481e' User entered 'No (N)'	System	22 Dec 2020 18:35:59
	System	22 Dec 2020 18:35:59

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Have you been exposed to someone with 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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-12-22T12:35:05', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'f04699e9-cee8-4a40-8d37-9121b1ba481e' User entered 'Yes (Y)'	System	22 Dec 2020 18:35:59
	System	22 Dec 2020 18:35:59

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Please 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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-12-22T12:35:28', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'f04699e9-cee8-4a40-8d37-9121b1ba481e'	System	22 Dec 2020 18:35:59
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Dec 2020 18:35:59

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2020-12-22T12:35:50', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'f04699e9-cee8-4a40-8d37-9121b1ba481e' User entered '22 Dec 2020 12:35:50'	System	22 Dec 2020 18:35:59
	System	22 Dec 2020 18:35:59



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 07:51:00

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 07:51:00

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 07:51:00

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 07:51:00

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-01-07T11:59:34', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'd180c05d-d6c1-405a-addb-cc4401e00bcb' User entered 'No (N)'	System	07 Jan 2021 18:00:03
	System	07 Jan 2021 18:00:03

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

Have you been exposed to someone with 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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-01-07T11:59:43', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'd180c05d-d6c1-405a-addb-cc4401e00bcb' User entered 'No (N)'	System	07 Jan 2021 18:00:03
	System	07 Jan 2021 18:00:03



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-01-07T11:59:59', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'd180c05d-d6c1-405a-addb-cc4401e00bcb' User entered '07 Jan 2021 11:59:59'	System	07 Jan 2021 18:00:03
	System	07 Jan 2021 18:00:03

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 07:51:00

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-01-12T12:00:39', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '8c07ccb4-2fd1-4e18-9ad6-02d665a9db71'	System	12 Jan 2021 18:01:17
User entered 'No (N)'	System	12 Jan 2021 18:01:17

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

Have you been exposed to someone with 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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-01-12T12:00:44', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '8c07ccb4-2fd1-4e18-9ad6-02d665a9db71'	System	12 Jan 2021 18:01:17
User entered 'No (N)'	System	12 Jan 2021 18:01:17

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-01-12T12:00:54', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '8c07ccb4-2fd1-4e18-9ad6-02d665a9db71' User entered '12 Jan 2021 12:00:54'	System	12 Jan 2021 18:01:17

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-01-19T12:04:20', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '16b55517-cd91-408b-9bfd-c4b6bf0c3397'	System	19 Jan 2021 18:04:29
User entered 'No (N)'	System	19 Jan 2021 18:04:29

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

Have you been exposed to someone with 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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-01-19T12:04:23', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '16b55517-cd91-408b-9bfd-c4b6bf0c3397'	System	19 Jan 2021 18:04:29
User entered 'No (N)'	System	19 Jan 2021 18:04:29

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-01-19T12:04:26', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '16b55517-cd91-408b-9bfd-c4b6bf0c3397'	System	19 Jan 2021 18:04:29
User entered '19 Jan 2021 12:04:26'	System	19 Jan 2021 18:04:29

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-01-27T12:07:31', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '919b0cb8-1f56-45b0-8df1-e54a6cfc7b10'	System	27 Jan 2021 18:07:44
User entered 'No (N)'	System	27 Jan 2021 18:07:44

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

Have you been exposed to someone with 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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-01-27T12:07:35', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '919b0cb8-1f56-45b0-8df1-e54a6cfc7b10'	System	27 Jan 2021 18:07:44
User entered 'No (N)'	System	27 Jan 2021 18:07:44

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-01-27T12:07:39', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '919b0cb8-1f56-45b0-8df1-e54a6cfc7b10' User entered '27 Jan 2021 12:07:39'	System	27 Jan 2021 18:07:44

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-01-31T11:57:11', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '9ad50c4a-24a0-475d-a76f-10ef8894fe37'	System	31 Jan 2021 17:57:20
User entered 'No (N)'	System	31 Jan 2021 17:57:20

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

Have you been exposed to someone with 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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-01-31T11:57:13', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '9ad50c4a-24a0-475d-a76f-10ef8894fe37'	System	31 Jan 2021 17:57:20
User entered 'No (N)'	System	31 Jan 2021 17:57:20



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-01-31T11:57:15', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '9ad50c4a-24a0-475d-a76f-10ef8894fe37'	System	31 Jan 2021 17:57:20
User entered '31 Jan 2021 11:57:15'	System	31 Jan 2021 17:57:20

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-02-09T18:14:51', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '6a71d260-de71-4652-a13a-bf746aba3934'	System	10 Feb 2021 00:18:15
User entered 'No (N)'	System	10 Feb 2021 00:18:15

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

Have you been exposed to someone with 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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-02-09T18:14:53', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '6a71d260-de71-4652-a13a-bf746aba3934'	System	10 Feb 2021 00:18:15
User entered 'No (N)'	System	10 Feb 2021 00:18:15

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-02-09T18:14:56', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '6a71d260-de71-4652-a13a-bf746aba3934'	System	10 Feb 2021 00:18:15
User entered '09 Feb 2021 18:14:56'	System	10 Feb 2021 00:18:15

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-02-16T12:07:01', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'fd39bcd9-ecbc-4e00-b0c5-3de2d629d272'	System	16 Feb 2021 18:10:25
User entered 'No (N)'	System	16 Feb 2021 18:10:25

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

Have you been exposed to someone with 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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-02-16T12:07:04', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'fd39bcd9-ecbc-4e00-b0c5-3de2d629d272'	System	16 Feb 2021 18:10:25
User entered 'No (N)'	System	16 Feb 2021 18:10:25

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-02-16T12:07:06', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'fd39bcd9-ecbc-4e00-b0c5-3de2d629d272' User entered '16 Feb 2021 12:07:06'	System	16 Feb 2021 18:10:25
	System	16 Feb 2021 18:10:25

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-02-25T12:18:41-06:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'dc237d8c-23b9-4780-9d6d-ed6c1e0532be' User entered 'No (N)'	System	25 Feb 2021 18:20:40
	System	25 Feb 2021 18:20:40

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

Have you been exposed to someone with 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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-02-25T12:18:47-06:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'dc237d8c-23b9-4780-9d6d-ed6c1e0532be'	System	25 Feb 2021 18:20:40
User entered 'No (N)'	System	25 Feb 2021 18:20:40

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-02-25T12:18:50-06:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'dc237d8c-23b9-4780-9d6d-ed6c1e0532be'	System	25 Feb 2021 18:20:40
User entered '25 Feb 2021 18:18:50'	System	25 Feb 2021 18:20:40

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 07:51:00

US3852177

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-02-28T09:21:53-06:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '8c74f240-a28d-4eb2-a41a-903048025d63'	System	28 Feb 2021 15:22:06
User entered 'No (N)'	System	28 Feb 2021 15:22:06

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Have you been exposed to someone with 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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-02-28T09:21:55-06:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '8c74f240-a28d-4eb2-a41a-903048025d63'	System	28 Feb 2021 15:22:06
User entered 'No (N)'	System	28 Feb 2021 15:22:06



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-02-28T09:22:04-06:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '8c74f240-a28d-4eb2-a41a-903048025d63' User entered '28 Feb 2021 15:22:04'	System	28 Feb 2021 15:22:06
	System	28 Feb 2021 15:22:06

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 07:51:00

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

[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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-03-07T00:02:52-06:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'c31955c5-c57c-4f5c-9098-760f9a4c5bf3'	System	07 Mar 2021 06:03:14
User entered 'Yes (Y)'	System	07 Mar 2021 06:03:14

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Have you been exposed to someone with 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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-03-07T00:02:56-06:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'c31955c5-c57c-4f5c-9098-760f9a4c5bf3'	System	07 Mar 2021 06:03:14
User entered 'No (N)'	System	07 Mar 2021 06:03:14

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-03-07T00:03:03-06:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'c31955c5-c57c-4f5c-9098-760f9a4c5bf3'	System	07 Mar 2021 06:03:14
User entered 'No (N)'	System	07 Mar 2021 06:03:14

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-03-07T00:03:08-06:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'c31955c5-c57c-4f5c-9098-760f9a4c5bf3'	System	07 Mar 2021 06:03:14
User entered 'No (N)'	System	07 Mar 2021 06:03:14



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-03-07T00:03:11-06:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'c31955c5-c57c-4f5c-9098-760f9a4c5bf3'	System	07 Mar 2021 06:03:14
User entered '07 Mar 2021 00:03:11'	System	07 Mar 2021 06:03:14

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 07:51:00

US3852177

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-03-16T12:30:23-05:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '15cd7ea3-b7c3-4e03-a7a5-4cc122ca3e83'	System	16 Mar 2021 17:30:38
User entered 'No (N)'	System	16 Mar 2021 17:30:38

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

Have you been exposed to someone with 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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-03-16T12:30:25-05:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '15cd7ea3-b7c3-4e03-a7a5-4cc122ca3e83'	System	16 Mar 2021 17:30:38
User entered 'No (N)'	System	16 Mar 2021 17:30:38

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-03-16T12:30:29-05:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '15cd7ea3-b7c3-4e03-a7a5-4cc122ca3e83'	System	16 Mar 2021 17:30:38
User entered '16 Mar 2021 12:30:29'	System	16 Mar 2021 17:30:38

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-03-21T00:24:54-05:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'e2e1abed-de10-49d7-b057-edd8f777bf03'	System	21 Mar 2021 05:25:05
User entered 'No (N)'	System	21 Mar 2021 05:25:05

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

Have you been exposed to someone with 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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-03-21T00:24:56-05:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'e2e1abed-de10-49d7-b057-edd8f777bf03'	System	21 Mar 2021 05:25:05
User entered 'No (N)'	System	21 Mar 2021 05:25:05

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-03-21T00:25:01-05:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'e2e1abed-de10-49d7-b057-edd8f777bf03'	System	21 Mar 2021 05:25:05
User entered '21 Mar 2021 00:25:01'	System	21 Mar 2021 05:25:05

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 07:51:00

US3852177

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-04-06T12:25:16-04:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '493d2f96-77a3-44aa-9e6b-60307cc55f6c' User entered 'No (N)'	System	06 Apr 2021 16:25:40
	System	06 Apr 2021 16:25:40

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

Have you been exposed to someone with 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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-04-06T12:25:18-04:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '493d2f96-77a3-44aa-9e6b-60307cc55f6c'	System	06 Apr 2021 16:25:40
User entered 'No (N)'	System	06 Apr 2021 16:25:40

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-04-06T12:25:35-04:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '493d2f96-77a3-44aa-9e6b-60307cc55f6c'	System	06 Apr 2021 16:25:40
User entered '06 Apr 2021 12:25:35'	System	06 Apr 2021 16:25:40

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-04-13T12:44:20-05:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '43832a7e-d967-4606-ab79-9d38ad5fac76'	System	13 Apr 2021 17:44:31
User entered 'No (N)'	System	13 Apr 2021 17:44:31

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

Have you been exposed to someone with 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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-04-13T12:44:25-05:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '43832a7e-d967-4606-ab79-9d38ad5fac76'	System	13 Apr 2021 17:44:31
User entered 'No (N)'	System	13 Apr 2021 17:44:31

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-04-13T12:44:27-05:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '43832a7e-d967-4606-ab79-9d38ad5fac76'	System	13 Apr 2021 17:44:31
User entered '13 Apr 2021 12:44:27'	System	13 Apr 2021 17:44:31

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-04-18T01:31:36-05:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'a68fc724-6c23-4433-8119-36e9f4d3b953'	System	18 Apr 2021 06:33:45
User entered 'Yes (Y)'	System	18 Apr 2021 06:33:45



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

Have you been exposed to someone with 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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-04-18T01:31:50-05:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'a68fc724-6c23-4433-8119-36e9f4d3b953'	System	18 Apr 2021 06:33:45
User entered 'No (N)'	System	18 Apr 2021 06:33:45

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-04-18T01:32:11-05:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'a68fc724-6c23-4433-8119-36e9f4d3b953'	System	18 Apr 2021 06:33:45
User entered 'Yes (Y)'	System	18 Apr 2021 06:33:45

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

Fever (Temperature  $\geq$  100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-04-18T01:32:57-05:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'a68fc724-6c23-4433-8119-36e9f4d3b953'	System	18 Apr 2021 06:33:45
User entered '1'	System	18 Apr 2021 06:33:45

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-04-18T01:32:57-05:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'a68fc724-6c23-4433-8119-36e9f4d3b953'	System	18 Apr 2021 06:33:45
User entered '1'	System	18 Apr 2021 06:33:45

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-04-18T01:32:57-05:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'a68fc724-6c23-4433-8119-36e9f4d3b953'	System	18 Apr 2021 06:33:45
User entered '1'	System	18 Apr 2021 06:33:45

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-04-18T01:32:57-05:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'a68fc724-6c23-4433-8119-36e9f4d3b953'	System	18 Apr 2021 06:33:45
User entered '1'	System	18 Apr 2021 06:33:45

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-04-18T01:32:57-05:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'a68fc724-6c23-4433-8119-36e9f4d3b953'	System	18 Apr 2021 06:33:45
User entered '1'	System	18 Apr 2021 06:33:45

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-04-18T01:32:57-05:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'a68fc724-6c23-4433-8119-36e9f4d3b953'	System	18 Apr 2021 06:33:45
User entered '1'	System	18 Apr 2021 06:33:45



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-04-18T01:32:57-05:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'a68fc724-6c23-4433-8119-36e9f4d3b953'	System	18 Apr 2021 06:33:45
User entered '1'	System	18 Apr 2021 06:33:45

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-04-18T01:32:57-05:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'a68fc724-6c23-4433-8119-36e9f4d3b953'	System	18 Apr 2021 06:33:45
User entered '1'	System	18 Apr 2021 06:33:45

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-04-18T01:32:57-05:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'a68fc724-6c23-4433-8119-36e9f4d3b953'	System	18 Apr 2021 06:33:45
User entered '1'	System	18 Apr 2021 06:33:45

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-04-18T01:32:57-05:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'a68fc724-6c23-4433-8119-36e9f4d3b953'	System	18 Apr 2021 06:33:45
User entered '0'	System	18 Apr 2021 06:33:45

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-04-18T01:32:57-05:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'a68fc724-6c23-4433-8119-36e9f4d3b953'	System	18 Apr 2021 06:33:45
User entered '0'	System	18 Apr 2021 06:33:45

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-04-18T01:32:57-05:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'a68fc724-6c23-4433-8119-36e9f4d3b953'	System	18 Apr 2021 06:33:45
User entered '0'	System	18 Apr 2021 06:33:45

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-04-18T01:32:57-05:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'a68fc724-6c23-4433-8119-36e9f4d3b953'	System	18 Apr 2021 06:33:45
User entered '1'	System	18 Apr 2021 06:33:45

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-04-18T01:32:57-05:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'a68fc724-6c23-4433-8119-36e9f4d3b953'	System	18 Apr 2021 06:33:45
User entered '1'	System	18 Apr 2021 06:33:45



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-04-18T01:32:57-05:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'a68fc724-6c23-4433-8119-36e9f4d3b953'	System	18 Apr 2021 06:33:45
User entered '0'	System	18 Apr 2021 06:33:45

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-04-18T01:32:57-05:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'a68fc724-6c23-4433-8119-36e9f4d3b953'	System	18 Apr 2021 06:33:45
User entered '0'	System	18 Apr 2021 06:33:45

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-04-18T01:32:57-05:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'a68fc724-6c23-4433-8119-36e9f4d3b953'	System	18 Apr 2021 06:33:45
User entered '0'	System	18 Apr 2021 06:33:45

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Please 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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-04-18T01:33:05-05:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'a68fc724-6c23-4433-8119-36e9f4d3b953'	System	18 Apr 2021 06:33:45
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Apr 2021 06:33:45

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

[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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-04-18T01:33:16-05:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'a68fc724-6c23-4433-8119-36e9f4d3b953'	System	18 Apr 2021 06:33:45
User entered 'Yes (Y)'	System	18 Apr 2021 06:33:45

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Please 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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-04-18T01:33:27-05:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'a68fc724-6c23-4433-8119-36e9f4d3b953'	System	18 Apr 2021 06:33:45
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Apr 2021 06:33:45

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-04-18T01:33:35-05:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: 'a68fc724-6c23-4433-8119-36e9f4d3b953'	System	18 Apr 2021 06:33:45
User entered '18 Apr 2021 01:33:35'	System	18 Apr 2021 06:33:45

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 07:51:00

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

[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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-04-25T00:02:18-05:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '5236700f-f7cb-46f8-a709-4a8498a16f5c' User entered 'No (N)'	System	25 Apr 2021 05:02:36
	System	25 Apr 2021 05:02:36

US3852177

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:04:53

Have you been exposed to someone with 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 (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-04-25T00:02:20-05:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '5236700f-f7cb-46f8-a709-4a8498a16f5c'	System	25 Apr 2021 05:02:36
User entered 'No (N)'	System	25 Apr 2021 05:02:36

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-04-25T00:02:23-05:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '5236700f-f7cb-46f8-a709-4a8498a16f5c'	System	25 Apr 2021 05:02:36
User entered '25 Apr 2021 00:02:23'	System	25 Apr 2021 05:02:36

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 07:51:00



**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 07:51:00

**US3852177**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:04:53**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:51:00
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 07:51:00

US3852177

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 10:04:53**

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)	24 Apr 2021 20:48:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-02-27T23:19:43-06:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '27e183ba-a961-4e24-bc2e-a830bb405733' User entered 'No (N)'	System	28 Feb 2021 05:19:57
	System	28 Feb 2021 05:19:57

US3852177

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:04:53

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:48:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (11A6659F-0047-4685-A6B3-8800DD163096)', Time: '2021-02-27T23:19:54-06:00', User OID: 'PatientReportedOutcome (US3852177)', ODM File OID: '27e183ba-a961-4e24-bc2e-a830bb405733' User entered '28 Feb 2021 05:19:54'	System	28 Feb 2021 05:19:57
	System	28 Feb 2021 05:19:57

US3852177

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:55:12
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	30 Nov 2020 22:48:37

US3852177

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:55:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '30 Nov 2020'	(b) (4) Martha Bunnell-Pollak (b) (4)	30 Nov 2020 22:48:37

US3852177

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:55:07
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Martha Bunnell-Pollak (b) (4)	30 Nov 2020 22:48:37

US3852177

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:22:27
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	30 Nov 2020 22:48:37



US3852177

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:56:40
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	30 Nov 2020 22:48:29

US3852177

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:12
User entered 'I'	System	30 Nov 2020 22:48:29

US3852177

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:19:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:58:47
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	04 Jan 2021 19:43:16

US3852177

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:19:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:58:49
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '4 Jan 2021'	(b) (4) Martha Bunnell-Pollak (b) (4)	04 Jan 2021 19:43:16

US3852177

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:19:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:58:51
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Martha Bunnell-Pollak (b) (4)	04 Jan 2021 19:43:16

US3852177

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:19:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:58:55
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	04 Jan 2021 19:43:16

US3852177

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:19:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 02:59:14
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	04 Jan 2021 19:43:19

US3852177

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:19:34
User entered 'I'	System	04 Jan 2021 19:43:19



US3852177

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:19:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:24:46
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 04:24:43
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:23:04
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:15:48

US3852177

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:19:34
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:23:24
User closed query 'Per Source, Contact occurred 02-FEB-2021. Please Clarifyt' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:56:44
	(b) (4), (b) (6)	16 Apr 2021 16:56:04
Query 'Per Source, Contact occurred 02-FEB-2021. Please Clarifyt' answered with 'Corrected' (Site from CRA).	Leslie Edwards (b) (4)	13 Apr 2021 13:47:30
Signature has been broken.	(b) (4)	
	Leslie Edwards (b) (4)	13 Apr 2021 13:47:14
User entered '2 Feb 2021' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per Source, Contact occurred 02-FEB-2021. Please Clarifyt' (Site from CRA).	Leslie Edwards (b) (4)	13 Apr 2021 13:47:14
DataPoint Un-verified.	(b) (4), (b) (6)	
	(b) (4), (b) (6)	13 Apr 2021 04:25:36
	(b) (4), (b) (6)	13 Apr 2021 04:24:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:23:06
User signature succeeded.	(b) (4)	
	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '1 Feb 2021'	(b) (4)	
	(b) (4), (b) (6)	08 Feb 2021 15:15:48

US3852177

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:19:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:23:08
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Feb 2021 15:15:48

US3852177

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:19:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:23:10
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4), (b) (6)	08 Feb 2021 15:15:48

US3852177

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:19:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:26:44
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Feb 2021 15:15:51

US3852177

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:19:34
User entered 'I'	System	08 Feb 2021 15:15:51

**US3852177**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:04:53**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:19:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:27:09
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 16:29:11

US3852177

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:19:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:27:11
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User entered '2 Mar 2021'	(b) (4), (b) (6)	02 Mar 2021 16:29:11



US3852177

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:19:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:27:12
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Mar 2021 16:29:11

US3852177

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:19:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:27:14
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 16:29:11

US3852177

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:19:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:27:23
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 16:29:18

US3852177

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 12:19:34
User entered 'I'	System	02 Mar 2021 16:29:18

US3852177

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:29:14
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:57:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Mar 2021 15:47:15

US3852177

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:53

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:29:15
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:57:56
User entered '25 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 15:47:15

US3852177

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:53

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:29:17
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:57:56
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	25 Mar 2021 15:47:15

**US3852177**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:04:53**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:49
User entered 'VISIT4'	System	25 Mar 2021 15:47:15



US3852177

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:04
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:57:56
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 18:38:10

US3852177

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:04
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:57:56
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:38:10

US3852177

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:04
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:57:56
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:38:10

US3852177

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:49
User entered empty.	System	30 Mar 2021 18:38:10

US3852177

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:04
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:57:56
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:38:10

US3852177

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:04
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:57:56
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:38:10

US3852177

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:04
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:57:56
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:38:10

US3852177

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:04
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:57:56
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:38:10



US3852177

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:49
User entered empty.	System	30 Mar 2021 18:38:10

US3852177

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:04
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:57:56
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:38:10

US3852177

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:49
User entered empty.	System	30 Mar 2021 18:38:10

US3852177

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:04
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:57:56
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:38:10

US3852177

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:49
User entered empty.	System	30 Mar 2021 18:38:10

US3852177

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:49
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:56:04
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:57:56
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 18:38:10

US3852177

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:49
User entered empty.	System	30 Mar 2021 18:38:10

US3852177

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:49



US3852177

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:04:53

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:49

US3852177

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:53

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:33:34
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:57:56
User entered 'No (N)'	(b) (4), (b) (6)	25 Mar 2021 15:47:45

US3852177

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:04:53

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:33:35
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:57:56
User entered empty.	(b) (4), (b) (6)	25 Mar 2021 15:47:45

US3852177

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:33:06
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:57:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Mar 2021 15:48:10

US3852177

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:33:07
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:57:56
User entered '25 Mar 2021'	(b) (4), (b) (6)	25 Mar 2021 15:48:10

**US3852177**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:04:53**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:33:09
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:57:56
User entered '10:38'	(b) (4), (b) (6)	25 Mar 2021 15:48:10

**US3852177**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:04:53**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:49
User entered '25 Mar 2021 10:38'	System	25 Mar 2021 15:48:10

US3852177

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:49
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:33:42
User signature succeeded.	Leland Allen (b) (4)	12 Apr 2021 20:57:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Mar 2021 15:48:18



US3852177

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:53

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:00:49
User entered 'I'	System	25 Mar 2021 15:48:18

US3852177

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	03 May 2021 21:14:07
	(b) (4)	
User entered 'Yes (Y)'	Martha Bunnell-Pollak	03 May 2021 14:31:16
	(b) (4)	

US3852177

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	03 May 2021 21:14:07
	(b) (4)	
User entered '3 May 2021'	Martha Bunnell-Pollak	03 May 2021 14:31:16
	(b) (4)	

US3852177

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	03 May 2021 21:14:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Martha Bunnell-Pollak (b) (4)	03 May 2021 14:31:16

US3852177

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:04:53

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	03 May 2021 21:14:07
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	03 May 2021 14:31:16

US3852177

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:04:53

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	03 May 2021 21:14:07
	(b) (4)	
User entered 'Yes (Y)'	Martha Bunnell-Pollak	03 May 2021 14:31:21
	(b) (4)	

**US3852177**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:04:53**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 14:31:21

US3852177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:04:53

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:35:14
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '18 Sep 2020'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	18 Sep 2020 20:20:35



US3852177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:04:53

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:35:15
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '14:58'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	18 Sep 2020 20:20:35

US3852177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:04:53

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:14
User entered '18 Sep 2020 14:58'	System	18 Sep 2020 20:20:35

US3852177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:04:53

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:35:17
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Safety Call (Safety Call)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	18 Sep 2020 20:20:35

US3852177

Folder: Covid-19 Assessment 18 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:04:53

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:14
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:35:19
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	18 Sep 2020 20:20:35

US3852177

Folder: Covid-19 Assessment 18 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 10:04:53

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:21
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:35:26
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	Jackie Ziegler (b) (4)	18 Sep 2020 20:20:43

US3852177

Folder: Covid-19 Assessment 25 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:04:53

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:38:47
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '25 Sep 2020'	Jessica Mcdowell (b) (4)	25 Sep 2020 15:14:56

US3852177

Folder: Covid-19 Assessment 25 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:04:53

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:38:48
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '11:10'	Jessica Mcdowell (b) (4)	25 Sep 2020 15:14:56

US3852177

Folder: Covid-19 Assessment 25 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:04:53

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:28
User entered '25 Sep 2020 11:10'	System	25 Sep 2020 15:14:56



US3852177

Folder: Covid-19 Assessment 25 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:04:53

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:38:50
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Safety Call (Safety Call)'	Jessica Mcdowell (b) (4)	25 Sep 2020 15:14:56

US3852177

Folder: Covid-19 Assessment 25 Sep 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:04:53

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:28
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:38:51
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	Jessica Mcdowell (b) (4)	25 Sep 2020 15:14:56

US3852177

Folder: Covid-19 Assessment 25 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 10:04:53

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:11:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:39:00
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	Jessica Mcdowell (b) (4)	25 Sep 2020 15:15:07

US3852177

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:53

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:37:31
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User entered 'Yes (Y)'	Lisa Huse (b) (4)	10 Feb 2021 14:25:02

US3852177

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:53

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:37:32
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User entered '10 Feb 2021'	(b) (4) Lisa Huse (b) (4) (b) (4)	10 Feb 2021 14:25:02

US3852177

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:53

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:37:34
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User entered 'Clinic (Clinic)'	Lisa Huse (b) (4)	10 Feb 2021 14:25:02

US3852177

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:04:53

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:51
User entered 'UNBLND_DECIDE'	System	10 Feb 2021 14:25:02

US3852177

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:04:53

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:39:31
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User entered '10 Feb 2021'	(b) (4) Lisa Huse (b) (4) (b) (4)	10 Feb 2021 14:37:14



**US3852177**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 10:04:53**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:51
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:54:34

US3852177

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:04:53

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:39:33
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User entered 'Yes (Y)'	(b) (4) Lisa Huse (b) (4) (b) (4)	10 Feb 2021 14:37:14

**US3852177**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 10:04:53**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:51
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:54:34

US3852177

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:04:53

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:39:35
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User entered '10 Feb 2021'	(b) (4) Lisa Huse (b) (4) (b) (4)	10 Feb 2021 14:37:14

US3852177

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:04:53

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:39:37
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User entered 'mRNA-1273 (mRNA-1273)'	Lisa Huse (b) (4)	10 Feb 2021 14:37:14

US3852177

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:04:53

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:39:38
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User entered 'mRNA-1273 (mRNA-1273)'	Lisa Huse (b) (4)	10 Feb 2021 14:37:14

US3852177

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:04:53

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:39:41
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User entered 'mRNA-1273 (mRNA-1273)'	Lisa Huse (b) (4)	10 Feb 2021 14:37:14

US3852177

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:04:53

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:39:44
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User entered 'No (N)'	(b) (4) Lisa Huse (b) (4) (b) (4)	10 Feb 2021 14:37:14



US3852177

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:04:53

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:51
User entered empty.	System	10 Feb 2021 14:37:14

US3852177

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:04:53

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:51
User entered empty.	System	10 Feb 2021 14:37:14

US3852177

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:40:01
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Feb 2021 16:26:30

US3852177

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:40:03
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User entered '10 Feb 2021'	(b) (4), (b) (6)	17 Feb 2021 16:26:30

US3852177

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:04:53

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:40:04
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User entered '08:35' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Feb 2021 16:27:21
User entered '08:30'	(b) (4), (b) (6)	17 Feb 2021 16:26:30

US3852177

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:04:53**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:51
User entered '10 Feb 2021 08:35'	System	17 Feb 2021 16:27:21
User entered '10 Feb 2021 08:30'	System	17 Feb 2021 16:26:30

US3852177

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:04:53

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:40:11
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Feb 2021 16:27:46

US3852177

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:04:53

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:40:13
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User entered '10 Feb 2021'	(b) (4), (b) (6)	17 Feb 2021 16:27:46



**US3852177**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 10:04:53**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:51
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:40:15
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User entered '08:30'	(b) (4), (b) (6)	17 Feb 2021 16:27:46

US3852177

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 10:04:53**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:24:51
User entered '10 Feb 2021 08:30'	System	17 Feb 2021 16:27:46

US3852177

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:04:53

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 04:46:29
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	08 Feb 2021 15:15:59
User closed query 'Per CDM: "Did the participant experience any adverse events?" is marked as No; however, data is recorded in the Adverse Events form. Please review and update accordingly. Thank you.	(b) (4), (b) (6)	03 Nov 2020 09:16:44
' (Site from DM).		
Query 'Per CDM: "Did the participant experience any adverse events?" is marked as No; however, data is recorded in the Adverse Events form. Please review and update accordingly. Thank you.	(b) (4), (b) (6)	27 Oct 2020 06:28:46
' answered with 'updated' (Site from DM).		
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	27 Oct 2020 06:28:40
User opened query 'Per CDM: "Did the participant experience any adverse events?" is marked as No; however, data is recorded in the Adverse Events form. Please review and update accordingly. Thank you.	(b) (4), (b) (6)	26 Oct 2020 07:39:36
' (Site from DM).		
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 20:09:45
User entered 'Yes (Y)'	Jackie Ziegler (b) (4) (b) (4)	18 Sep 2020 20:20:51

US3852177

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:53

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:59:33

US3852177

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:53

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:59:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:31:41
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Reproductive tract disorders NEC, HLT: Reproductive tract signs and symptoms NEC, PT: Perineal rash, LLT: Perineal rash - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 17:38:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 17:38:35
User closed query 'Per DM CLR: Please review AE and please update to specify whether the reported AE of Rash is Urticarial or Non-urticarial. Please update and reconcile applicable eCFRs so there would be an appropriate match.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 12:42:22
Data point term sent to Coder	System	10 Nov 2020 14:26:57
Query 'Per DM CLR: Please review AE and please update to specify whether the reported AE of Rash is Urticarial or Non-urticarial. Please update and reconcile applicable eCFRs so there would be an appropriate match.' answered with 'Updated' (Site from DM).	Leslie Edwards (b) (4)	10 Nov 2020 14:26:49
Coding entries removed.	Leslie Edwards (b) (4)	10 Nov 2020 14:26:44
User entered 'RED, BLISTERED RASH IN PERINEAL AREA; SKIN EPIDERMAL DISORDER-Non-urticarial' reason for change: Data Entry Error	Leslie Edwards (b) (4)	10 Nov 2020 14:26:44
User opened query 'Per DM CLR: Please review AE and please update to specify whether the reported AE of Rash is Urticarial or Non-urticarial. Please update and reconcile applicable eCFRs so there would be an appropriate match.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 03:41:03
User closed query "'Per MM: Please code this way: SOC: Skin and subcutaneous tissue disorders  HLGT: Epidermal and dermal conditions  HLT: Rashes, eruptions and exanthems NEC  PT: Rash vesicular  LLT: Blistery rash"' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 11:51:31

US3852177

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:53

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Reproductive tract disorders NEC, HLT: Reproductive tract signs and symptoms NEC, PT: Perineal rash, LLT: Perineal rash - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 09:54:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Oct 2020 09:54:41
Data point term sent to Coder	System	16 Oct 2020 06:51:52
Query "'Per MM: Please code this way: SOC: Skin and subcutaneous tissue disorders HLGT: Epidermal and dermal conditions HLT: Rashes, eruptions and exanthems NEC PT: Rash vesicular LLT: Blistery rash" ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 06:51:12
Coding entries removed.	(b) (4), (b) (6)	16 Oct 2020 06:50:58
User entered 'RED, BLISTERED RASH IN PERINEAL AREA; Skin epidermal disorder' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 06:50:58
User opened query "'Per MM: Please code this way: SOC: Skin and subcutaneous tissue disorders HLGT: Epidermal and dermal conditions HLT: Rashes, eruptions and exanthems NEC PT: Rash vesicular LLT: Blistery rash" ' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 06:43:23
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Bullous conditions, PT: Blister, LLT: Blister - version MedDRA\\23.0.	Coder Import (b) (4)	03 Oct 2020 05:10:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	03 Oct 2020 05:10:54
Data point term sent to Coder	System	02 Oct 2020 18:32:20
User entered 'Red, blistered rash in perineal area'	Martha Bunnell-Pollak (b) (4)	02 Oct 2020 18:31:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:59:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:31:41
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	(b) (4) Martha Bunnell-Pollak (b) (4)	02 Oct 2020 18:31:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:59:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:31:41
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	(b) (4) Martha Bunnell-Pollak (b) (4)	02 Oct 2020 18:31:39



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:59:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:31:41
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	(b) (4) Martha Bunnell-Pollak (b) (4)	02 Oct 2020 18:31:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:59:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:31:41
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '28 Sep 2020'	(b) (4) Martha Bunnell-Pollak (b) (4)	02 Oct 2020 18:31:39

**US3852177**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:04:53**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:59:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:31:41
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	02 Oct 2020 18:31:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:53

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:59:33
User entered empty.	System	02 Oct 2020 18:31:39

**US3852177**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:04:53**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:59:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:31:41
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
User entered 'Yes (Y)'	Leslie Edwards (b) (4)	19 Nov 2020 16:19:43
	(b) (4)	
	Martha Bunnell-Pollak	02 Oct 2020 18:31:39
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:04:53**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:59:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:31:41
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '13 Oct 2020' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Leslie Edwards (b) (4)	19 Nov 2020 16:19:43
	(b) (4)	
	Martha Bunnell-Pollak	02 Oct 2020 18:31:39
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:04:53**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:59:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:31:41
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	02 Oct 2020 18:31:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:53

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:59:33
User entered empty.	System	02 Oct 2020 18:31:39



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:53

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:59:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:31:41
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Martha Bunnell-Pollak (b) (4)	02 Oct 2020 18:31:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:59:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:31:41
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	(b) (4) Martha Bunnell-Pollak (b) (4)	02 Oct 2020 18:31:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:53

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:59:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:31:41
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '0'	(b) (4) Martha Bunnell-Pollak (b) (4)	02 Oct 2020 18:31:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:53

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:59:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:31:41
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '0'	(b) (4) Martha Bunnell-Pollak (b) (4)	02 Oct 2020 18:31:39

**US3852177**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:04:53**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:59:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:31:41
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '0'	(b) (4) Martha Bunnell-Pollak (b) (4)	02 Oct 2020 18:31:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:59:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:31:41
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	02 Oct 2020 18:31:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:53

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:59:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:31:41
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	02 Oct 2020 18:31:39

**US3852177**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:04:53**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:59:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:31:41
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	02 Oct 2020 18:31:39



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:04:53**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:59:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:31:41
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	02 Oct 2020 18:31:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:59:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:31:41
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '0'	(b) (4) Martha Bunnell-Pollak (b) (4)	02 Oct 2020 18:31:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:59:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:31:41
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '0'	(b) (4) Martha Bunnell-Pollak (b) (4)	02 Oct 2020 18:31:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:53

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:59:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:31:41
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '0'	(b) (4) Martha Bunnell-Pollak (b) (4)	02 Oct 2020 18:31:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:59:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:31:41
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Oct 2020 06:50:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Oct 2020 06:50:58
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 06:50:58
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 18:31:39
User entered empty.	Martha Bunnell-Pollak (b) (4)	02 Oct 2020 18:31:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:59:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:31:41
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Oct 2020 06:50:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Oct 2020 06:50:58
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 06:50:58
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 18:31:39
User entered empty.	Martha Bunnell-Pollak (b) (4)	02 Oct 2020 18:31:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:53

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:59:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:31:41
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	16 Oct 2020 06:50:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Oct 2020 06:50:58
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 06:50:58
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 18:31:39
User entered empty.	Martha Bunnell-Pollak (b) (4)	02 Oct 2020 18:31:39

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:53

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:59:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:31:41
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #5 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Jan 2021 16:20:43
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #5 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.' answered with 'Updated' (Site from DM).	Leslie Edwards (b) (4) (b) (4)	15 Jan 2021 15:49:07
User entered '0' reason for change: Data Entry Error	Leslie Edwards (b) (4)	15 Jan 2021 15:48:45
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #5 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Dec 2020 01:49:24
User entered '1'	Martha Bunnell-Pollak (b) (4)	02 Oct 2020 18:31:39



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:59:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:31:41
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Leslie Edwards (b) (4)	15 Jan 2021 15:48:45
User entered '0'	(b) (4)	
	Martha Bunnell-Pollak	02 Oct 2020 18:31:39
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:04:53**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:59:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:31:41
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '0'	(b) (4) Martha Bunnell-Pollak (b) (4)	02 Oct 2020 18:31:39

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:04:53**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:59:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:31:41
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4) Leslie Edwards (b) (4)	19 Nov 2020 16:19:43
Data Entry Error	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Martha Bunnell-Pollak (b) (4)	02 Oct 2020 18:31:39

**US3852177**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:04:53**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:59:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:31:41
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	02 Oct 2020 18:31:39

**US3852177**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:04:53**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:59:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:31:41
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	02 Oct 2020 18:31:39

**US3852177**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:04:53**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:59:33
User entered '0'	System	02 Oct 2020 18:31:39

**US3852177**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:04:53**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:59:33
User entered '0'	System	02 Oct 2020 18:31:39

US3852177

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:04:53

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 04:59:33



US3852177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:53

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:37:33
User entered	System	19 Apr 2021 20:37:29
'USA-US076-2021-mRNA-1273-P301000004'		
User entered 'New' reason for change: New	(b) (4), (b) (6)	19 Apr 2021 20:37:29
Information		
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 20:37:01

US3852177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:53

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 13:52:35
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Apr 2021 13:52:35
	(b) (4)	
Data point term sent to Coder	System	19 Apr 2021 13:52:09
User entered 'Pneumonia'	(b) (4), (b) (6)	19 Apr 2021 13:51:44

**US3852177**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:04:53**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Apr 2021 13:51:44

US3852177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 13:51:44

US3852177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
User entered 'No (N)'	(b) (4), (b) (6)	19 Apr 2021 13:51:44

US3852177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
User entered '13 Apr 2021'	(b) (4), (b) (6)	19 Apr 2021 13:51:44

US3852177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:53

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	19 Apr 2021 13:52:18
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 13:52:18
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	19 Apr 2021 13:51:44
User entered '08:00'	(b) (4), (b) (6)	19 Apr 2021 13:51:44

**US3852177**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:04:53**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 13:52:18
User entered '13 Apr 2021 08:00'	System	19 Apr 2021 13:51:44



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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:53

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per MM, please provide the end date. ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 20:39:46
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
Query 'Per MM, please provide the end date. ' answered with 'Ongoing' (Site from DM).	Lisa Huse (b) (4)	28 Apr 2021 17:45:23
User opened query 'Per MM, please provide the end date. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 18:36:32
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:17:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Apr 2021 13:51:44

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:53

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 13:51:44

**US3852177**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:04:53**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 13:51:44

**US3852177**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:04:53**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 13:51:44

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:53

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	19 Apr 2021 13:51:44

US3852177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Apr 2021 13:51:44

US3852177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:53

Death

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
User entered '0'	(b) (4), (b) (6)	19 Apr 2021 13:51:44

US3852177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
User entered '0'	(b) (4), (b) (6)	19 Apr 2021 13:51:44



US3852177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Per CDM Re-query: Site response indicates data updated, however, please update 'Other Action taken' field on this form, as it is expected some medication is taken for ongoing Pneumonia that requires inpatient or prolongation of existing Hospitalization.' (Site from DM).	(b) (4), (b) (6)	01 May 2021 06:23:04
Query 'Per CDM Re-query: Site response indicates data updated, however, please update 'Other Action taken' field on this form, as it is expected some medication is taken for ongoing Pneumonia that requires inpatient or prolongation of existing Hospitalization.' answered with 'other action has been updated to indicated medication that is ongoing. ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 23:08:13
User opened query 'Per CDM Re-query: Site response indicates data updated, however, please update 'Other Action taken' field on this form, as it is expected some medication is taken for ongoing Pneumonia that requires inpatient or prolongation of existing Hospitalization.' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 20:42:05
User closed query 'Per CDM RQ : Site response noted, kindly review and update the data when it is available. until please open the query. Thank you ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 20:40:07
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
Query 'Per CDM RQ : Site response noted, kindly review and update the data when it is available. until please open the query. Thank you ' answered with 'information updated' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 17:28:23
User opened query 'Per CDM RQ : Site response noted, kindly review and update the data when it is available. until please open the query. Thank you ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 11:22:23
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	26 Apr 2021 11:18:38
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:17:25

US3852177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Subject is still admitted-data will be updated when subject is discharged.' (Site from System).	Leslie Edwards (b) (4)	19 Apr 2021 14:02:37
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	19 Apr 2021 13:51:44
User entered '1'	(b) (4), (b) (6)	19 Apr 2021 13:51:44

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
User entered '16 Apr 2021'	(b) (4), (b) (6)	19 Apr 2021 13:51:44

US3852177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:53

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 17:26:46
User entered '19 Apr 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Apr 2021 17:26:46
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:17:25
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 13:51:44

US3852177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User closed query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	26 Apr 2021 17:26:46
Query 'Admitted to ICU?' is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		26 Apr 2021 17:26:46
DataPoint Un-verified.	(b) (4), (b) (6)	26 Apr 2021 17:26:46
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Apr 2021 17:26:46
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:17:25
User opened query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	19 Apr 2021 13:51:44
User entered 'Unknown (UNK)'	(b) (4), (b) (6)	19 Apr 2021 13:51:44

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 13:51:44

US3852177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
User entered '0'	(b) (4), (b) (6)	19 Apr 2021 13:51:44

US3852177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
User entered '0'	(b) (4), (b) (6)	19 Apr 2021 13:51:44



US3852177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
User entered '0'	(b) (4), (b) (6)	19 Apr 2021 13:51:44

US3852177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	19 Apr 2021 13:51:44

US3852177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	19 Apr 2021 13:51:44

US3852177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:53

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	19 Apr 2021 13:51:44

US3852177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:53

None

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	30 Apr 2021 17:17:59
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 23:07:42
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 23:07:42
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 23:07:42
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	19 Apr 2021 14:01:48
User entered '1' reason for change: Data Entry Error	Leslie Edwards (b) (4)	19 Apr 2021 14:01:48
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
	System	19 Apr 2021 13:51:44
User entered '0'	(b) (4), (b) (6)	19 Apr 2021 13:51:44

US3852177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	30 Apr 2021 17:17:59
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 23:07:42
Signature has been broken.	(b) (4), (b) (6)	29 Apr 2021 23:07:42
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 23:07:42
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
User entered '0'	(b) (4), (b) (6)	19 Apr 2021 13:51:44

US3852177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
User entered '0'	(b) (4), (b) (6)	19 Apr 2021 13:51:44

US3852177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:53

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	19 Apr 2021 13:51:44



US3852177

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 10:04:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 13:51:44

**US3852177**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:04:53**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
User entered empty.	(b) (4), (b) (6)	19 Apr 2021 13:51:44

**US3852177**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:04:53**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 13:51:44

**US3852177**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:04:53**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 13:51:44

**US3852177**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 10:04:53**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Apr 2021 13:51:44

US3852177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:53

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux - version MedDRA\\23.0.	Coder Import (b) (4)	28 Apr 2021 19:14:37
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Apr 2021 19:14:37
	(b) (4)	
Data point term sent to Coder	System	28 Apr 2021 17:47:41
User entered 'Reflux'	Lisa Huse (b) (4)	28 Apr 2021 17:46:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:53

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'Yes (Y)'		
	Lisa Huse (b) (4)	28 Apr 2021 17:46:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:53

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'No (N)'		
	Lisa Huse (b) (4)	28 Apr 2021 17:46:58
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:53

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'No (N)'		
	Lisa Huse (b) (4)	28 Apr 2021 17:46:58
	(b) (4)	

US3852177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered '19 Apr 2021'		
	Lisa Huse (b) (4)	28 Apr 2021 17:46:58
	(b) (4)	

US3852177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:53

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered empty.		
	Lisa Huse (b) (4)	28 Apr 2021 17:46:58
	(b) (4)	

**US3852177**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 10:04:53**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 17:46:58

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'Yes (Y)'		
	Lisa Huse (b) (4)	28 Apr 2021 17:46:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:53

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered empty.		
	Lisa Huse (b) (4)	28 Apr 2021 17:46:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:53

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered empty.		
	Lisa Huse (b) (4)	28 Apr 2021 17:46:58
	(b) (4)	

**US3852177**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 10:04:53**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Apr 2021 17:46:58



US3852177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:53

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Lisa Huse (b) (4) (b) (4)	28 Apr 2021 17:46:58

US3852177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:53

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'No (N)'		
	Lisa Huse (b) (4)	28 Apr 2021 17:46:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:53

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered '0'		
	Lisa Huse (b) (4)	28 Apr 2021 17:46:58
	(b) (4)	

US3852177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered '0'		
	Lisa Huse (b) (4)	28 Apr 2021 17:46:58
	(b) (4)	

US3852177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered '0'		
	Lisa Huse (b) (4)	28 Apr 2021 17:46:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:53

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered empty.		
	Lisa Huse (b) (4)	28 Apr 2021 17:46:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:53

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered empty.		
	Lisa Huse (b) (4)	28 Apr 2021 17:46:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:53

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered empty.		
	Lisa Huse (b) (4)	28 Apr 2021 17:46:58
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:53

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered empty.		
	Lisa Huse (b) (4)	28 Apr 2021 17:46:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered '0'		
	Lisa Huse (b) (4)	28 Apr 2021 17:46:58
	(b) (4)	

US3852177

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered '0'		
	Lisa Huse (b) (4)	28 Apr 2021 17:46:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered '0'		
	Lisa Huse (b) (4)	28 Apr 2021 17:46:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:53

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'Not Related (NOT RELATED)'	(b) (4)	
	Lisa Huse (b) (4)	28 Apr 2021 17:46:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:53

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'Not Related (NOT RELATED)'		
	Lisa Huse (b) (4)	28 Apr 2021 17:46:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:53

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'Not Applicable (NOT APPLICABLE)'	Lisa Huse (b) (4)	28 Apr 2021 17:46:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:53

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered '0'		
	Lisa Huse (b) (4)	28 Apr 2021 17:46:58
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:53

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'I'		
	Lisa Huse (b) (4)	28 Apr 2021 17:46:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:53

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered '0'		
	Lisa Huse (b) (4)	28 Apr 2021 17:46:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:53

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Lisa Huse (b) (4)	28 Apr 2021 17:46:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:53

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered empty.		
	Lisa Huse (b) (4)	28 Apr 2021 17:46:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 10:04:53

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered empty.		
	Lisa Huse (b) (4)	28 Apr 2021 17:46:58
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 10:04:53**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	28 Apr 2021 17:46:58

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 10:04:53**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Apr 2021 17:46:58

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:04:53

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:25:45
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:31:54
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
Signature has been broken.	(b) (4), (b) (6)	02 Mar 2021 16:30:13
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Mar 2021 16:30:13
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Feb 2021 15:16:06
User closed query 'Per CDM: "Were any ConMeds taken?" is marked as No; however, data is recorded in the ConMed form. Please review and update accordingly. Thank you. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 12:19:13
Query 'Per CDM: "Were any ConMeds taken?" is marked as No; however, data is recorded in the ConMed form. Please review and update accordingly. Thank you. ' answered with 'Corrected' (Site from DM).	Leslie Edwards (b) (4)	05 Nov 2020 20:14:46
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	05 Nov 2020 20:14:42
User opened query 'Per CDM: "Were any ConMeds taken?" is marked as No; however, data is recorded in the ConMed form. Please review and update accordingly. Thank you. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 08:16:42
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 20:09:56
User entered 'Yes (Y)'	Jackie Ziegler (b) (4)	18 Sep 2020 20:28:34



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:53

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 16:34:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 16:34:01
Data point term sent to Coder Coding entries removed.	System Leslie Edwards (b) (4)	19 Nov 2020 16:18:14 19 Nov 2020 16:18:08
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 20:30:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Sep 2020 20:30:38
Data point term sent to Coder User entered 'losartan'	System Jackie Ziegler (b) (4)	18 Sep 2020 20:29:55 18 Sep 2020 20:29:05

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:04:53**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	18 Sep 2020 20:29:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Hypertension' reason for change: Data Entry Error	(b) (4)	19 Nov 2020 16:18:08
User entered 'HTN'	Jackie Ziegler (b) (4)	18 Sep 2020 20:29:05
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:04:53**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
	(b) (4)	
Signature has been broken.	Lisa Huse (b) (4)	28 Apr 2021 17:43:07
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
	(b) (4)	
User entered '50'	Jackie Ziegler (b) (4)	18 Sep 2020 20:29:05
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'mg (mg)'	(b) (4) Jackie Ziegler (b) (4)	18 Sep 2020 20:29:05

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:04:53**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	18 Sep 2020 20:29:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'once daily (QD)'	Jackie Ziegler (b) (4)	18 Sep 2020 20:29:05

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:04:53**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	18 Sep 2020 20:29:05



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:04:53**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Oral (ORAL)'	Jackie Ziegler (b) (4)	18 Sep 2020 20:29:05

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:04:53**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	18 Sep 2020 20:29:05

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:04:53**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	18 Sep 2020 20:29:05

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:04:53**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'I'	Jackie Ziegler (b) (4)	18 Sep 2020 20:29:05

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:04:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	Jackie Ziegler (b) (4)	18 Sep 2020 20:29:05

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:04:53**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	Jackie Ziegler (b) (4)	18 Sep 2020 20:29:05

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:04:53**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:06
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	Jackie Ziegler (b) (4)	18 Sep 2020 20:29:05

**US3852177**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:04:53**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 20:29:05



US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:04:53**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 20:29:05

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:04:53**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 20:29:05

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:53

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:08
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Sep 2020 20:30:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 20:30:38
Data point term sent to Coder	System	18 Sep 2020 20:29:55
User entered 'montelukast'	Jackie Ziegler (b) (4) (b) (4)	18 Sep 2020 20:29:47

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:08
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	Jackie Ziegler (b) (4)	18 Sep 2020 20:29:47

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:04:53**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:08
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'asthma'	Jackie Ziegler (b) (4)	18 Sep 2020 20:29:47

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:08
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '10'	Jackie Ziegler (b) (4)	18 Sep 2020 20:29:47

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:08
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'mg (mg)'	(b) (4) Jackie Ziegler (b) (4)	18 Sep 2020 20:29:47

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:04:53**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:08
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	18 Sep 2020 20:29:47



US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:08
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'once daily (QD)'	Jackie Ziegler (b) (4)	18 Sep 2020 20:29:47

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:04:53**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:08
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	18 Sep 2020 20:29:47

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:08
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Oral (ORAL)'	Jackie Ziegler (b) (4)	18 Sep 2020 20:29:47

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:04:53**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:08
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	18 Sep 2020 20:29:47

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:08
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	18 Sep 2020 20:29:47

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:04:53**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:08
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'I'	Jackie Ziegler (b) (4)	18 Sep 2020 20:29:47

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:08
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	18 Sep 2020 20:29:47

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:04:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:08
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	18 Sep 2020 20:29:47



US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:04:53**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:08
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	18 Sep 2020 20:29:47

**US3852177**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:04:53**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 20:29:47

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:04:53**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 20:29:47

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:04:53**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 20:29:47

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:53

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:10
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM TARTRATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Sep 2020 20:31:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 20:31:39
Data point term sent to Coder	System	18 Sep 2020 20:30:56
User entered 'zolpidem tartrate'	Jackie Ziegler (b) (4) (b) (4)	18 Sep 2020 20:30:25

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:10
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	18 Sep 2020 20:30:25

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:04:53**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:10
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'insomnia'	Jackie Ziegler (b) (4)	18 Sep 2020 20:30:25

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:10
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '10'	Jackie Ziegler (b) (4)	18 Sep 2020 20:30:25



US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:10
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'mg (mg)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	18 Sep 2020 20:30:25

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:53

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:10
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	18 Sep 2020 20:30:25
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:10
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'once daily (QD)'	Jackie Ziegler (b) (4)	18 Sep 2020 20:30:25

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:53

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:10
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	18 Sep 2020 20:30:25

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:04:53**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:10
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Oral (ORAL)'	Jackie Ziegler (b) (4)	18 Sep 2020 20:30:25

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:04:53**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:10
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	18 Sep 2020 20:30:25

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:04:53**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:10
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	18 Sep 2020 20:30:25

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:04:53**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:10
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'I'	Jackie Ziegler (b) (4)	18 Sep 2020 20:30:25



US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:04:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:10
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	18 Sep 2020 20:30:25

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:04:53**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:10
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	Jackie Ziegler (b) (4)	18 Sep 2020 20:30:25

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:04:53**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:10
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4)	18 Sep 2020 20:30:25

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:04:53**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 20:30:25

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:04:53**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 20:30:25

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:04:53**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 20:30:25

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:53

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Sep 2020 20:32:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 20:32:43
Data point term sent to Coder	System	18 Sep 2020 20:31:57
User entered 'atorvastatin'	Jackie Ziegler (b) (4) (b) (4)	18 Sep 2020 20:31:05

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	(b) (4) Jackie Ziegler (b) (4) (b) (4)	18 Sep 2020 20:31:05



US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:04:53**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'hyperlipidemia'	Jackie Ziegler (b) (4)	18 Sep 2020 20:31:05

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:04:53**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '20'	Jackie Ziegler (b) (4)	18 Sep 2020 20:31:05

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'mg (mg)'	(b) (4) Jackie Ziegler (b) (4)	18 Sep 2020 20:31:05

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:04:53**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	18 Sep 2020 20:31:05

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'once daily (QD)'	Jackie Ziegler (b) (4)	18 Sep 2020 20:31:05

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:53

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4) Jackie Ziegler (b) (4) (b) (4)	18 Sep 2020 20:31:05

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:53

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Oral (ORAL)'	Jackie Ziegler (b) (4)	18 Sep 2020 20:31:05

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:04:53**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	18 Sep 2020 20:31:05



US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	18 Sep 2020 20:31:05

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:04:53**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'I'	Jackie Ziegler (b) (4)	18 Sep 2020 20:31:05

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:53

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4) Jackie Ziegler (b) (4)	18 Sep 2020 20:31:05

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:04:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4) Jackie Ziegler (b) (4)	18 Sep 2020 20:31:05

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:04:53**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:11
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	Jackie Ziegler (b) (4)	18 Sep 2020 20:31:05

**US3852177**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:04:53**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 20:31:05

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:04:53**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 20:31:05

**US3852177**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:04:53**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 20:31:05



US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:07:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:17
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: TRIAMCINOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 14:00:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 14:00:08
Data point term sent to Coder	System	26 Feb 2021 16:21:18
Coding entries removed.	Leslie Edwards (b) (4) (b) (4)	26 Feb 2021 16:21:11
User signature succeeded.	Leland Allen (b) (4) (b) (4)	09 Feb 2021 10:55:37
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: TRIAMCINOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Feb 2021 15:12:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Feb 2021 15:12:51
User closed query 'Per DM CLR: Please provide the strength of this topical medication in the medication name as there are multiple dosage options for this drug. Review and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 16:38:34
Data point term sent to Coder	System	03 Feb 2021 20:25:51
Query 'Per DM CLR: Please provide the strength of this topical medication in the medication name as there are multiple dosage options for this drug. Review and amend as appropriate. ' answered with 'Updated' (Site from DM).	Leslie Edwards (b) (4) (b) (4)	03 Feb 2021 20:25:16

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US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:53

Name of Medication

Audit	User	Time (GMT)
Coding entries removed.	Leslie Edwards (b) (4)	03 Feb 2021 20:25:10
User entered 'TRIAMCINOLONE CREAM 0.05%' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Please provide the strength of this topical medication in the medication name as there are multiple dosage options for this drug. Review and amend as appropriate. ' (Site from DM).	Leslie Edwards (b) (4)	03 Feb 2021 20:25:10
	(b) (4)	
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: TRIAMCINOLONE - version WHODrug-Global-B3\\202003.	(b) (4), (b) (6)	01 Feb 2021 09:29:29
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: TRIAMCINOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 17:25:44
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 17:25:44
	(b) (4)	
Data point term sent to Coder	System	27 Oct 2020 15:42:40
User entered 'triamcinolone cream'	Martha Bunnell-Pollak	27 Oct 2020 15:42:20
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:07:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:17
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	(b) (4) Martha Bunnell-Pollak (b) (4)	27 Oct 2020 15:42:20

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:53

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:07:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:17
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User closed query 'Per DM CLR: Please update the indication and clarify the type of RASH (urticarial vs non-urticarial). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Mar 2021 02:06:49
Query 'Per DM CLR: Please update the indication and clarify the type of RASH (urticarial vs non-urticarial). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'Updated' (Site from DM).	Leslie Edwards (b) (4) (b) (4)	26 Feb 2021 16:21:25
Signature has been broken.	Leslie Edwards (b) (4) (b) (4)	26 Feb 2021 16:21:11
User entered 'RASH IN PERINEAL AREA-non-urticarial' reason for change: Data Entry Error	Leslie Edwards (b) (4) (b) (4)	26 Feb 2021 16:21:11
User opened query 'Per DM CLR: Please update the indication and clarify the type of RASH (urticarial vs non-urticarial). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 19:10:18
User signature succeeded.	Leland Allen (b) (4) (b) (4)	09 Feb 2021 10:55:37
User closed query 'Per DM CLR: Please provide the strength of this topical medication in the medication name. Review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 16:55:56
User closed query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 16:55:09

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:53

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please provide the strength of this topical medication in the medication name. Review and amend as appropriate.' answered with 'Updated' (Site from DM).	Leslie Edwards (b) (4) (b) (4)	15 Jan 2021 15:50:26
Query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' answered with 'Updated' (Site from DM).	Leslie Edwards (b) (4) (b) (4)	15 Jan 2021 15:49:30
User opened query 'Per DM CLR: Please provide the strength of this topical medication in the medication name. Review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6) (b) (4)	07 Jan 2021 12:46:23
User opened query 'Per DM CLR: Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6) (b) (4)	07 Jan 2021 12:46:09
User entered 'Rash in perineal area'	Martha Bunnell-Pollak (b) (4)	27 Oct 2020 15:42:20

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:07:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:17
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '1' reason for change: Data Entry Error	(b) (4)	03 Feb 2021 20:25:10
User entered '0.05' reason for change: Data Entry Error	Leslie Edwards (b) (4)	15 Jan 2021 15:50:21
User entered '1'	Martha Bunnell-Pollak (b) (4)	27 Oct 2020 15:42:20

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:07:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:17
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Other (OTHER)'	(b) (4) Martha Bunnell-Pollak (b) (4)	27 Oct 2020 15:42:20

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:07:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:17
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'application' reason for change: Data Entry Error	(b) (4)	03 Feb 2021 20:25:10
User entered 'Percent' reason for change: Data Entry Error	Leslie Edwards (b) (4)	15 Jan 2021 15:50:21
User entered 'application'	(b) (4)	27 Oct 2020 15:42:20
	Martha Bunnell-Pollak	
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:07:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:17
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'twice daily (BID)' reason for change:	(b) (4)	
Data Entry Error	Leslie Edwards (b) (4)	13 Nov 2020 15:27:34
User entered 'other (OTHER)'	(b) (4)	
	Martha Bunnell-Pollak	27 Oct 2020 15:42:20
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:53

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:07:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:17
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User closed query 'Per CDM: Please review "Frequency" and update with either an appropriate frequency time or "as needed" if used as needed by the patient. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Nov 2020 10:33:38
Query 'Per CDM: Please review "Frequency" and update with either an appropriate frequency time or "as needed" if used as needed by the patient. Thank you. ' answered with 'Corrected' (Site from DM).	Leslie Edwards (b) (4) (b) (4)	13 Nov 2020 15:27:43
User entered empty; reason for change Data Entry Error	Leslie Edwards (b) (4) (b) (4)	13 Nov 2020 15:27:34
User opened query 'Per CDM: Please review "Frequency" and update with either an appropriate frequency time or "as needed" if used as needed by the patient. Thank you. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 10:52:09
User entered 'as directed'	Martha Bunnell-Pollak (b) (4)	27 Oct 2020 15:42:20

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:04:53**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:07:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:17
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Topical (TOPICAL)'	(b) (4) Martha Bunnell-Pollak (b) (4)	27 Oct 2020 15:42:20

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:04:53**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:07:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:17
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	27 Oct 2020 15:42:20

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:07:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:17
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '29 Sep 2020'	(b) (4) Martha Bunnell-Pollak (b) (4)	27 Oct 2020 15:42:20

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:04:53**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:07:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:17
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '0'	(b) (4) Martha Bunnell-Pollak (b) (4)	27 Oct 2020 15:42:20

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:07:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:17
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	19 Nov 2020 16:19:14
User entered 'Yes (Y)'	Martha Bunnell-Pollak (b) (4)	27 Oct 2020 15:42:20

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:04:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:07:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:17
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '13 Oct 2020' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Leslie Edwards (b) (4)	19 Nov 2020 16:19:14
	(b) (4)	
	Martha Bunnell-Pollak	27 Oct 2020 15:42:20
	(b) (4)	



**US3852177**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:04:53**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:07:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:17
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	(b) (4) Martha Bunnell-Pollak (b) (4)	27 Oct 2020 15:42:20

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:04:53**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:07:59
User entered '2'	System	13 Nov 2020 15:27:34
User entered empty.	System	27 Oct 2020 15:42:20

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:04:53**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:07:59
User entered '1'	System	13 Nov 2020 15:27:34
User entered empty.	System	27 Oct 2020 15:42:20

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:04:53**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:07:59
User entered '804 (804)'	System	13 Nov 2020 15:27:34
User entered empty.	System	27 Oct 2020 15:42:20

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:53

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Nov 2020 22:51:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Nov 2020 22:51:15
Data point term sent to Coder	System	30 Nov 2020 22:50:08
User entered 'Influenza Vaccine'	Martha Bunnell-Pollak (b) (4)	30 Nov 2020 22:49:43

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:53

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Yes (Y)'	(b) (4) Martha Bunnell-Pollak (b) (4)	30 Nov 2020 22:49:43

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:04:53**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Flu shot'	(b) (4) Martha Bunnell-Pollak (b) (4)	30 Nov 2020 22:49:43

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:53

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of injection/vaccine count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 16:38:43
Query 'Per DM CLR: Please provide the actual dose for this medication instead of injection/vaccine count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'Updated' (Site from DM).	Leslie Edwards (b) (4) (b) (4)	03 Feb 2021 20:25:44
User entered '0.5' reason for change: Data Entry Error	Leslie Edwards (b) (4) (b) (4)	03 Feb 2021 20:25:39
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of injection/vaccine count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 09:29:38
User entered 'I'	Martha Bunnell-Pollak (b) (4)	30 Nov 2020 22:49:43



US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:53

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'mL (mL)' reason for change: Data Entry Error	(b) (4)	
	Leslie Edwards (b) (4)	03 Feb 2021 20:25:39
User entered 'Other (OTHER)'	(b) (4)	
	Martha Bunnell-Pollak	30 Nov 2020 22:49:43
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:53

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty; reason for change Data Entry Error	(b) (4)	
	Leslie Edwards (b) (4)	03 Feb 2021 20:25:39
User entered 'injection'	(b) (4)	
	Martha Bunnell-Pollak	30 Nov 2020 22:49:43
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:53

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'once (ONCE)'	(b) (4) Martha Bunnell-Pollak (b) (4)	30 Nov 2020 22:49:43

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:04:53**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	30 Nov 2020 22:49:43

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:04:53**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Martha Bunnell-Pollak (b) (4)	30 Nov 2020 22:49:43

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:04:53**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered empty.	(b) (4) Martha Bunnell-Pollak (b) (4)	30 Nov 2020 22:49:43

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:04:53**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '30 Nov 2020'	(b) (4) Martha Bunnell-Pollak (b) (4)	30 Nov 2020 22:49:43

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:04:53**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '0'	(b) (4) Martha Bunnell-Pollak (b) (4)	30 Nov 2020 22:49:43



US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:53

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	(b) (4) Martha Bunnell-Pollak (b) (4)	30 Nov 2020 22:49:43

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:04:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered '30 Nov 2020'	(b) (4) Martha Bunnell-Pollak (b) (4)	30 Nov 2020 22:49:43

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:04:53**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:04
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:21
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	(b) (4) Martha Bunnell-Pollak (b) (4)	30 Nov 2020 22:49:43

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:04:53**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:04
User entered empty.	System	30 Nov 2020 22:49:43

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:04:53**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:04
User entered empty.	System	30 Nov 2020 22:49:43

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:04:53**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:04
User entered empty.	System	30 Nov 2020 22:49:43

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:53

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:24
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: BABY ASPIRIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Mar 2021 16:32:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 16:32:43
Data point term sent to Coder	System	02 Mar 2021 16:31:29
User entered 'Baby Aspirin'	(b) (4), (b) (6)	02 Mar 2021 16:31:11

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:53

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:24
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:31:11



US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:53

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:24
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User entered 'Blood thinner'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:31:11

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:53

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:24
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User entered '81'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:31:11

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:53

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:24
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:31:11

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:04:53**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:24
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:31:11

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:04:53

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:24
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:31:11

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:04:53**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:24
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:31:11

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:04:53**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:24
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:31:11

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:04:53**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:24
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:31:11



US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:04:53**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:24
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:31:11

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:04:53**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:24
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:31:11

**US3852177**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:04:53**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:24
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:31:11

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:04:53**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:24
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:31:11

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:04:53**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:32:24
User signature succeeded.	Leland Allen (b) (4)	15 Mar 2021 04:37:58
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 16:31:11

**US3852177**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:04:53**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Mar 2021 16:31:11

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:04:53**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Mar 2021 16:31:11

**US3852177**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:04:53**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Mar 2021 16:31:11



US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:04:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
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: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE, PRODUCTSYNONYM: PEPCID [FAMOTIDINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Apr 2021 19:01:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Apr 2021 19:01:57
Data point term sent to Coder	System	28 Apr 2021 17:40:34
User entered 'Pepcid'	Lisa Huse (b) (4)	28 Apr 2021 17:39:35
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:04:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'No (N)'		
	Lisa Huse (b) (4)	28 Apr 2021 17:39:35
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:04:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'Reflux'	Lisa Huse (b) (4)	28 Apr 2021 17:39:35
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:04:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered '20'	Lisa Huse (b) (4)	28 Apr 2021 17:39:35
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:04:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'mg (mg)'	Lisa Huse (b) (4)	28 Apr 2021 17:39:35
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:04:53

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered empty.		
	Lisa Huse (b) (4)	28 Apr 2021 17:39:35
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:04:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'once daily (QD)'		
	Lisa Huse (b) (4)	28 Apr 2021 17:39:35
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:04:53

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered empty.		
	Lisa Huse (b) (4)	28 Apr 2021 17:39:35
	(b) (4)	



US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:04:53**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'Oral (ORAL)'		
	Lisa Huse (b) (4)	28 Apr 2021 17:39:35
	(b) (4)	

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:04:53**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered empty.		
	Lisa Huse (b) (4)	28 Apr 2021 17:39:35
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:04:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered '19 Apr 2021'		
	Lisa Huse (b) (4)	28 Apr 2021 17:39:35
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:04:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered '0'		
	Lisa Huse (b) (4)	28 Apr 2021 17:39:35
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:04:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'Yes (Y)'	Lisa Huse (b) (4)	28 Apr 2021 17:39:35
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:04:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered empty.		
	Lisa Huse (b) (4)	28 Apr 2021 17:39:35
	(b) (4)	

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:04:53**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'No (N)'		
	Lisa Huse (b) (4)	28 Apr 2021 17:39:35
	(b) (4)	

**US3852177**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:04:53**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 17:39:35



US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:04:53**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 17:39:35

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:04:53**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Apr 2021 17:39:35

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:04:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE FUROATE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: BREO ELLIPTA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Apr 2021 19:29:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	28 Apr 2021 17:41:34
User entered 'Brio'	Lisa Huse (b) (4)	28 Apr 2021 17:40:40
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:04:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'No (N)'		
	Lisa Huse (b) (4)	28 Apr 2021 17:40:40
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:04:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'Pneumonia'	Lisa Huse (b) (4)	28 Apr 2021 17:40:40
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:04:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'Unknown'		
	Lisa Huse (b) (4)	28 Apr 2021 17:40:40
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:04:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'Other (OTHER)'		
	Lisa Huse (b) (4)	28 Apr 2021 17:40:40
	(b) (4)	

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:04:53**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'Unknown'		
	Lisa Huse (b) (4)	28 Apr 2021 17:40:40
	(b) (4)	



US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:04:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'twice daily (BID)'	Lisa Huse (b) (4)	28 Apr 2021 17:40:40
	(b) (4)	

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:04:53**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered empty.		
	Lisa Huse (b) (4)	28 Apr 2021 17:40:40
	(b) (4)	

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:04:53**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Lisa Huse (b) (4)	28 Apr 2021 17:40:40
	(b) (4)	

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:04:53**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered empty.		
	Lisa Huse (b) (4)	28 Apr 2021 17:40:40
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:04:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered '19 Apr 2021'		
	Lisa Huse (b) (4)	28 Apr 2021 17:40:40
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:04:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered '0'		
	Lisa Huse (b) (4)	28 Apr 2021 17:40:40
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:04:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'Yes (Y)'		
	Lisa Huse (b) (4)	28 Apr 2021 17:40:40
	(b) (4)	

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:04:53**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered empty.		
	Lisa Huse (b) (4)	28 Apr 2021 17:40:40
	(b) (4)	



US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:04:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'No (N)'		
	Lisa Huse (b) (4)	28 Apr 2021 17:40:40
	(b) (4)	

**US3852177**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:04:53**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	28 Apr 2021 17:40:40

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:04:53**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 17:40:40

**US3852177**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:04:53**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Apr 2021 17:40:40

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:04:53

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFDINIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Apr 2021 19:03:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Apr 2021 19:03:14
Data point term sent to Coder	System	28 Apr 2021 17:42:36
User entered 'Cefdinir'	Lisa Huse (b) (4)	28 Apr 2021 17:41:41
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:04:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'No (N)'		
	Lisa Huse (b) (4)	28 Apr 2021 17:41:41
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:04:53

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'Pneumonia'	Lisa Huse (b) (4)	28 Apr 2021 17:41:41
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:04:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered '300'		
	Lisa Huse (b) (4)	28 Apr 2021 17:41:41
	(b) (4)	



US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:04:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'mg (mg)'		
	Lisa Huse (b) (4)	28 Apr 2021 17:41:41
	(b) (4)	

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:04:53**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered empty.		
	Lisa Huse (b) (4)	28 Apr 2021 17:41:41
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:04:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'once daily (QD)'	(b) (4)	
	Lisa Huse (b) (4)	28 Apr 2021 17:41:41
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:04:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered empty.		
	Lisa Huse (b) (4)	28 Apr 2021 17:41:41
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:04:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'Oral (ORAL)'	(b) (4)	
	Lisa Huse (b) (4)	28 Apr 2021 17:41:41
	(b) (4)	

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:04:53**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered empty.		
	Lisa Huse (b) (4)	28 Apr 2021 17:41:41
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:04:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered '19 Apr 2021'		
	Lisa Huse (b) (4)	28 Apr 2021 17:41:41
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:04:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered '0'		
	Lisa Huse (b) (4)	28 Apr 2021 17:41:41
	(b) (4)	



US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:04:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	03 May 2021 21:14:07
	(b) (4)	
DataPoint Un-verified.	Martha Bunnell-Pollak	03 May 2021 18:46:42
	(b) (4)	
Signature has been broken.	Martha Bunnell-Pollak	03 May 2021 18:46:42
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Martha Bunnell-Pollak	03 May 2021 18:46:42
	(b) (4)	
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'Yes (Y)'	Lisa Huse (b) (4)	28 Apr 2021 17:41:41
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:04:53

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	03 May 2021 21:14:07
	(b) (4)	
DataPoint Un-verified.	Martha Bunnell-Pollak	03 May 2021 18:46:42
	(b) (4)	
Signature has been broken.	Martha Bunnell-Pollak	03 May 2021 18:46:42
	(b) (4)	
User entered '19 Apr 2021' reason for change: New Information	Martha Bunnell-Pollak	03 May 2021 18:46:42
	(b) (4)	
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered empty.	Lisa Huse (b) (4)	28 Apr 2021 17:41:41
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:04:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'No (N)'		
	Lisa Huse (b) (4)	28 Apr 2021 17:41:41
	(b) (4)	

**US3852177**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:04:53**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 17:41:41

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:04:53**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 17:41:41

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:04:53**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Apr 2021 17:41:41

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:04:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Apr 2021 19:03:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Apr 2021 19:03:13
Data point term sent to Coder	System	28 Apr 2021 17:42:35
User entered 'Prednisone'	Lisa Huse (b) (4)	28 Apr 2021 17:42:29
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:04:53

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'No (N)'		
	Lisa Huse (b) (4)	28 Apr 2021 17:42:29
	(b) (4)	



US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 10:04:53**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'Pneumonia'		
	Lisa Huse (b) (4)	28 Apr 2021 17:42:29
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:04:53

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered '10'	Lisa Huse (b) (4)	28 Apr 2021 17:42:29
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:04:53

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'mg (mg)'		
	Lisa Huse (b) (4)	28 Apr 2021 17:42:29
	(b) (4)	

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 10:04:53**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered empty.		
	Lisa Huse (b) (4)	28 Apr 2021 17:42:29
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:04:53

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'once daily (QD)'	Lisa Huse (b) (4)	28 Apr 2021 17:42:29
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:04:53

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered empty.		
	Lisa Huse (b) (4)	28 Apr 2021 17:42:29
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:04:53

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'Oral (ORAL)'		
	Lisa Huse (b) (4)	28 Apr 2021 17:42:29
	(b) (4)	

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 10:04:53**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered empty.		
	Lisa Huse (b) (4)	28 Apr 2021 17:42:29
	(b) (4)	



US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:04:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered '19 Apr 2021'		
	Lisa Huse (b) (4)	28 Apr 2021 17:42:29
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:04:53

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered '0'		
	Lisa Huse (b) (4)	28 Apr 2021 17:42:29
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:04:53

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'No (N)'		
	Lisa Huse (b) (4)	28 Apr 2021 17:42:29
	(b) (4)	

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 10:04:53**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered '26 Apr 2021'		
	Lisa Huse (b) (4)	28 Apr 2021 17:42:29
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:04:53

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	29 Apr 2021 12:46:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 22:37:28
User entered 'No (N)'		
	Lisa Huse (b) (4)	28 Apr 2021 17:42:29
	(b) (4)	

**US3852177**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 10:04:53**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 17:42:29

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 10:04:53**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 17:42:29

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 10:04:53**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	28 Apr 2021 17:42:29



US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:04:53

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	03 May 2021 21:14:07
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	03 May 2021 18:49:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 May 2021 18:49:24
Data point term sent to Coder	System	03 May 2021 18:48:32
User entered 'Pneumonia Vaccine'	Martha Bunnell-Pollak (b) (4)	03 May 2021 18:47:40

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:04:53**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	03 May 2021 21:14:07
	(b) (4)	
User entered 'Yes (Y)'	Martha Bunnell-Pollak	03 May 2021 18:47:40
	(b) (4)	

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:04:53**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	03 May 2021 21:14:07
User entered 'Prevention of pneumonia'	(b) (4) Martha Bunnell-Pollak (b) (4)	03 May 2021 18:47:40

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:04:53**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	03 May 2021 21:14:07
User entered '1'	(b) (4)	
	Martha Bunnell-Pollak	03 May 2021 18:47:40
	(b) (4)	

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:04:53**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	03 May 2021 21:14:07
	(b) (4)	
User entered 'Other (OTHER)'	Martha Bunnell-Pollak	03 May 2021 18:47:40
	(b) (4)	

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:04:53**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	03 May 2021 21:14:07
	(b) (4)	
User entered 'injection'	Martha Bunnell-Pollak	03 May 2021 18:47:40
	(b) (4)	

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:04:53**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	03 May 2021 21:14:07
	(b) (4)	
User entered 'once (ONCE)'	Martha Bunnell-Pollak	03 May 2021 18:47:40
	(b) (4)	

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:04:53**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	03 May 2021 21:14:07
	(b) (4)	
User entered empty.	Martha Bunnell-Pollak	03 May 2021 18:47:40
	(b) (4)	



US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:04:53**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	03 May 2021 21:14:07
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4)	
	Martha Bunnell-Pollak	03 May 2021 18:47:40
	(b) (4)	

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:04:53**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	03 May 2021 21:14:07
	(b) (4)	
User entered empty.	Martha Bunnell-Pollak	03 May 2021 18:47:40
	(b) (4)	

US3852177

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:04:53

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	03 May 2021 21:14:07
User entered '30 Apr 2021'	(b) (4) Martha Bunnell-Pollak (b) (4)	03 May 2021 18:47:40

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:04:53**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	03 May 2021 21:14:07
	(b) (4)	
User entered '0'	Martha Bunnell-Pollak	03 May 2021 18:47:40
	(b) (4)	

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:04:53**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	03 May 2021 21:14:07
	(b) (4)	
User entered 'No (N)'	Martha Bunnell-Pollak	03 May 2021 18:47:40
	(b) (4)	

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:04:53**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	03 May 2021 21:14:07
	(b) (4)	
User entered '30 Apr 2021'	Martha Bunnell-Pollak	03 May 2021 18:47:40
	(b) (4)	

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:04:53**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	03 May 2021 21:14:07
User entered 'No (N)'	(b) (4) Martha Bunnell-Pollak (b) (4)	03 May 2021 18:47:40

**US3852177**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:04:53**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 18:47:40



US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:04:53**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 18:47:40

US3852177

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:04:53**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 May 2021 18:47:40

US3852177

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 10 Jun 2021 10:04:53**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 04:31:00
User signature succeeded.	Leland Allen (b) (4)	09 Feb 2021 10:55:37
User entered 'No (N)'	Jackie Ziegler (b) (4)	18 Sep 2020 20:31:10

US3852177

Folder: SAE USA-US076-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:23:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:37:51
User entered		
'USA-US076-2021-MRNA-1273-P301000004'	System	19 Apr 2021 20:37:29

**US3852177**

**Folder: SAE USA-US076-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:04:53**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:23:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:37:51
User entered 'Yes (Y)'	System	19 Apr 2021 20:37:29

**US3852177**

**Folder: SAE USA-US076-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:04:53**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:23:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:37:51
User entered 'No (N)'	System	19 Apr 2021 20:37:29

US3852177

Folder: SAE USA-US076-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:23:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:37:51
User entered 'No (N)'	System	19 Apr 2021 20:37:29

**US3852177**

**Folder: SAE USA-US076-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:04:53**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:23:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:37:51
User entered 'Yes (Y)'	System	19 Apr 2021 20:37:29



US3852177

Folder: SAE USA-US076-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:23:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:37:51
User entered 'No (N)'	System	19 Apr 2021 20:37:29

US3852177

Folder: SAE USA-US076-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:23:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:37:51
User entered 'No (N)'	System	19 Apr 2021 20:37:29

US3852177

Folder: SAE USA-US076-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:23:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:37:51
User entered 'No (N)'	System	19 Apr 2021 20:37:29

US3852177

Folder: SAE USA-US076-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:23:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:37:51
User entered 'Leland'	System	19 Apr 2021 20:37:29

US3852177

Folder: SAE USA-US076-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:23:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:37:51
User entered 'Allen'	System	19 Apr 2021 20:37:29

US3852177

Folder: SAE USA-US076-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:53

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:40:48
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:23:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:17:25
User entered 'US'	System	19 Apr 2021 20:39:03

**US3852177**

**Folder: SAE USA-US076-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:04:53**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	30 Apr 2021 13:40:44
User entered '1'	System	19 Apr 2021 20:39:03

US3852177

Folder: SAE USA-US076-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:23:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:37:51
User entered		
'USA-US076-2021-MRNA-1273-P301000004'	System	19 Apr 2021 20:37:29



US3852177

Folder: SAE USA-US076-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:23:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:37:51
User entered 'Yes (Y)'	System	19 Apr 2021 20:37:29

**US3852177**

**Folder: SAE USA-US076-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:04:53**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:23:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:37:51
User entered 'No (N)'	System	19 Apr 2021 20:37:29

US3852177

Folder: SAE USA-US076-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:23:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:37:51
User entered 'No (N)'	System	19 Apr 2021 20:37:29

US3852177

Folder: SAE USA-US076-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:53

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:23:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:37:51
User entered 'Yes (Y)'	System	19 Apr 2021 20:37:29

US3852177

Folder: SAE USA-US076-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:23:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:37:51
User entered 'No (N)'	System	19 Apr 2021 20:37:29

US3852177

Folder: SAE USA-US076-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:23:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:37:51
User entered 'No (N)'	System	19 Apr 2021 20:37:29

US3852177

Folder: SAE USA-US076-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:23:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:37:51
User entered 'No (N)'	System	19 Apr 2021 20:37:29

US3852177

Folder: SAE USA-US076-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:23:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:37:51
User entered 'Leland'	System	19 Apr 2021 20:37:29



US3852177

Folder: SAE USA-US076-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:23:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:37:51
User entered 'Allen'	System	19 Apr 2021 20:37:29

US3852177

Folder: SAE USA-US076-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:53

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:40:48
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:23:24
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:17:25
User entered 'US'	System	19 Apr 2021 20:39:03

**US3852177**

**Folder: SAE USA-US076-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:04:53**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	30 Apr 2021 13:40:44
User entered '1'	System	19 Apr 2021 20:39:03

**US3852177**

**Folder: SAE USA-US076-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 10:04:53**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:23:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
User entered '19/Apr/2021 16:39'	System	19 Apr 2021 20:39:03

US3852177

Folder: SAE USA-US076-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:04:53

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:40:48
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:23:24
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:17:25
User entered 'I'	(b) (4), (b) (6)	19 Apr 2021 20:39:03

US3852177

Folder: SAE USA-US076-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:53

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:23:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:37:51
User entered		
'USA-US076-2021-MRNA-1273-P301000004'	System	19 Apr 2021 20:37:29

US3852177

Folder: SAE USA-US076-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:53

Serious

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:23:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:37:51
User entered 'Yes (Y)'	System	19 Apr 2021 20:37:29

**US3852177**

**Folder: SAE USA-US076-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:04:53**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:23:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:37:51
User entered 'No (N)'	System	19 Apr 2021 20:37:29



US3852177

Folder: SAE USA-US076-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:53

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:23:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:37:51
User entered 'No (N)'	System	19 Apr 2021 20:37:29

**US3852177**

**Folder: SAE USA-US076-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:04:53**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:23:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:37:51
User entered 'Yes (Y)'	System	19 Apr 2021 20:37:29

US3852177

Folder: SAE USA-US076-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:53

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:23:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:37:51
User entered 'No (N)'	System	19 Apr 2021 20:37:29

US3852177

Folder: SAE USA-US076-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:53

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:23:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:37:51
User entered 'No (N)'	System	19 Apr 2021 20:37:29

US3852177

Folder: SAE USA-US076-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:53

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:23:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:37:51
User entered 'No (N)'	System	19 Apr 2021 20:37:29

US3852177

Folder: SAE USA-US076-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:53

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:23:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:37:51
User entered 'Leland'	System	19 Apr 2021 20:37:29

US3852177

Folder: SAE USA-US076-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:53

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:23:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:25
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 20:37:51
User entered 'Allen'	System	19 Apr 2021 20:37:29

US3852177

Folder: SAE USA-US076-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 10 Jun 2021 10:04:53

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:40:48
User signature succeeded.	Leland Allen (b) (4)	26 Apr 2021 01:23:24
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:17:25
User entered 'US'	System	19 Apr 2021 20:39:03



**US3852177**

**Folder: SAE USA-US076-2021-MRNA-1273-P301000004**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:04:53**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	30 Apr 2021 13:40:44
User entered '1'	System	19 Apr 2021 20:39:03

**US3852177**

**Folder: SAE USA-US076-2021-MRNA-1273-P301000004**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 10:04:53**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	30 Apr 2021 17:17:59
User entered '30/Apr/2021 09:40'	(b) (4) System	30 Apr 2021 13:40:44

US3852177

Folder: SAE USA-US076-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:04:53

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Leland Allen (b) (4)	30 Apr 2021 17:17:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 13:40:48
User entered 'I'	(b) (4), (b) (6)	30 Apr 2021 13:40:44