

US3772007 (Prod: Paradigm Clinical Research Institute Inc - ClinEdge - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:46:07

All time stamps listed in this document are displayed in GMT

US3772007

Form: Participant Creation

Data signed: (b) (4) 16 Sep 2020 17:11:59

Generated On: 10 Jun 2021 09:46:07

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[Participant ID](#)

US3772007

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

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US3772007

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 16 Sep 2020 17:11:59

Generated On: 10 Jun 2021 09:46:07

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

Visit date (dd MMM yyyy)	05 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3772007

Folder: Screening

Form: Demographics

Data signed: (b) (4) 16 Sep 2020 17:11:58

Generated On: 10 Jun 2021 09:46:07

Date of Birth (MMM yyyy)	(b) (6) 1986
Age	33
Age Units	YEARS
Age (Derived)	33
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	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) 16 Sep 2020 17:11:58

Generated On: 10 Jun 2021 09:46:07

Date of Informed Consent ( <i>dd MMM yyyy</i> )	05 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3772007

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 16 Sep 2020 17:11:58

Generated On: 10 Jun 2021 09:46:07

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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) 16 Sep 2020 17:11:59

Generated On: 10 Jun 2021 09:46:07

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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) 31 Mar 2021 19:29:24

Generated On: 10 Jun 2021 09:46:07

Condition	BILATERAL SALPINGECTOMY
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 31 Mar 2021 19:29:24

Generated On: 10 Jun 2021 09:46:07

Condition	CESAREAN SECTION
Start date (dd MMM yyyy)	UN UNK 2007
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2007
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2007
Stop Year (derived)	2007

US3772007

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 31 Mar 2021 19:29:24

Generated On: 10 Jun 2021 09:46:07

Condition	CESAREAN SECTION
Start date (dd MMM yyyy)	UN UNK 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2011
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	JAN 2011
Stop Year (derived)	2011

US3772007

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 31 Mar 2021 19:29:24

Generated On: 10 Jun 2021 09:46:07

Condition	NICOTINE ADDICTION (1 PACK PER DAY)
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 16 Sep 2020 17:11:59

Generated On: 10 Jun 2021 09:46:07

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	05 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	08:40 (24 HR)
Vital Signs Date and Time (derived)	05 AUG 2020 08:40
Height ( <i>xxx.x</i> )	156 cm
Weight ( <i>xxx.x</i> )	42.3 kg
BMI ( <i>xxx.x</i> )	17.38166 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 16 Sep 2020 17:11:59

Generated On: 10 Jun 2021 09:46:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 16 Sep 2020 17:11:58

Generated On: 10 Jun 2021 09:46:07

Date of assessment (dd MMM yyyy) 05 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

If Partner medically sterile or Other, specify \_\_\_\_\_

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 2013

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) \_\_\_\_\_

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 16 Sep 2020 17:11:59

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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) 16 Sep 2020 17:11:59

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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) 16 Sep 2020 17:11:59

Generated On: 10 Jun 2021 09:46:07

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 16 Sep 2020 17:11:59

Generated On: 10 Jun 2021 09:46:07

What was the date of randomization? (dd MMM yyyy) 05 AUG 2020

What was the participant's randomization number? 101130

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Sep 2020 17:11:59

Generated On: 10 Jun 2021 09:46:07

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) 16 Sep 2020 17:11:59

Generated On: 10 Jun 2021 09:46:07

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)	05 AUG 2020
Time of assessment (00:00-23:59)	08:40 (24 HR)
Vital Signs Date and Time (derived)	05 AUG 2020 08:40
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	90 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Sep 2020 17:11:59

Generated On: 10 Jun 2021 09:46:07

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)	05 AUG 2020
Time of assessment (00:00-23:59)	09:57 (24 HR)
Vital Signs Date and Time (derived)	05 AUG 2020 09:57
Temperature (xxx.x)	37.4 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3772007

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 16 Sep 2020 17:11:59

Generated On: 10 Jun 2021 09:46:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Sep 2020 17:11:58

Generated On: 10 Jun 2021 09:46:07

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) 05 AUG 2020

What was the treatment time? (00:00-23:59) 09:22 (24 HR)

Treatment Date and Time (derived) 05 AUG 2020 09:22

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Sep 2020 17:11:58

Generated On: 10 Jun 2021 09:46:07

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	05 AUG 2020
Collection time (00:00-23:59)	09:07 (24 HR)
Collection date and time (derived)	05 AUG 2020 09:07



US3772007

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Sep 2020 17:11:59

Generated On: 10 Jun 2021 09:46:07

Collection date (dd MMM yyyy)			05 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:12	05 AUG 2020 09:12
Nasopharyngeal Swab 2	No		

US3772007

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Sep 2020 17:11:58

Generated On: 10 Jun 2021 09:46:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

**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

99.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 AUG 2020 09:59

PC Open Date & Time

05 AUG 2020 09:42

PC Close Date & Time

05 AUG 2020 12:12

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 99.4 °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	05 AUG 2020 21:01
PC Open Date & Time	05 AUG 2020 13:07
PC Close Date & Time	06 AUG 2020 11:59

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:46:07

**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

98.8 °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

06 AUG 2020 13:59

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:46:07

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

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Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.7 °F

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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 AUG 2020 15:39

---

PC Open Date & Time

07 AUG 2020 12:00

---

PC Close Date & Time

08 AUG 2020 11:59

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US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 12:10

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:46:07

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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

98.6 °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

09 AUG 2020 17:14

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PC Open Date & Time

09 AUG 2020 12:00

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PC Close Date & Time

10 AUG 2020 11:59

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US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:46:07

**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

98.4 °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

11 AUG 2020 09:07

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

12 AUG 2020 08:44

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

**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

05 AUG 2020 10:00

PC Open Date & Time

05 AUG 2020 09:42

PC Close Date & Time

05 AUG 2020 12:12

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 AUG 2020 21:01

PC Open Date & Time

05 AUG 2020 13:07

PC Close Date & Time

06 AUG 2020 11:59

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 AUG 2020 14:00

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:46:07

**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

07 AUG 2020 15:39

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:46:07

**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

08 AUG 2020 12:10

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:46:07

**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

09 AUG 2020 17:14

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59



US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:46:07

**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 AUG 2020 09:08

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:46:07

**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

12 AUG 2020 08:44

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

**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 ☐

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

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

No ☒

Yes ☐

PC Time stamp	05 AUG 2020 10:00
PC Open Date & Time	05 AUG 2020 09:42
PC Close Date & Time	05 AUG 2020 12:12

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

**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 ☐

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

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

No ☒

Yes ☐

PC Time stamp	05 AUG 2020 21:02
PC Open Date & Time	05 AUG 2020 13:07
PC Close Date & Time	06 AUG 2020 11:59

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:46:07

**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 ☒

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:46:07

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 14:00
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59



US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:46:07

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:46:07

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 15:40
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:46:07

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 12:11
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:46:07

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 ☒

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:46:07

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 17:15
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:46:07

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

54 of 1852

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:46:07

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 09:08
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59



US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

**DAY 7**

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

56 of 1852

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:46:07

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 08:45
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3772007

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Sep 2020 17:11:59

Generated On: 10 Jun 2021 09:46:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3772007

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Sep 2020 17:11:58

Generated On: 10 Jun 2021 09:46:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772007

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Sep 2020 17:11:59

Generated On: 10 Jun 2021 09:46:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3772007

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Sep 2020 17:11:58

Generated On: 10 Jun 2021 09:46:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772007

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Sep 2020 17:11:59

Generated On: 10 Jun 2021 09:46:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3772007

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Sep 2020 17:11:58

Generated On: 10 Jun 2021 09:46:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3772007

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Sep 2020 17:11:59

Generated On: 10 Jun 2021 09:46:07

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3772007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Sep 2020 17:11:59

Generated On: 10 Jun 2021 09:46:07

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)	08 SEP 2020
Time of assessment (00:00-23:59)	15:45 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 15:45
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3772007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Sep 2020 17:11:59

Generated On: 10 Jun 2021 09:46:07

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)	08 SEP 2020
Time of assessment (00:00-23:59)	17:30 (24 HR)
Vital Signs Date and Time (derived)	08 SEP 2020 17:30
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3772007

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Sep 2020 17:11:59

Generated On: 10 Jun 2021 09:46:07

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 SEP 2020

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

US3772007

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Sep 2020 17:11:58

Generated On: 10 Jun 2021 09:46:07

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) 08 SEP 2020

What was the treatment time? (00:00-23:59) 16:54 (24 HR)

Treatment Date and Time (derived) 08 SEP 2020 16:54

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

US3772007

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Sep 2020 17:11:58

Generated On: 10 Jun 2021 09:46:07

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

08 SEP 2020

Collection time (00:00-23:59)

16:00 (24 HR)

Collection date and time (derived)

08 SEP 2020 16:00

US3772007

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Sep 2020 17:11:59

Generated On: 10 Jun 2021 09:46:07

Collection date (dd MMM yyyy)			08 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:05	08 SEP 2020 16:05
Nasopharyngeal Swab 2	No		

US3772007

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Sep 2020 17:11:58

Generated On: 10 Jun 2021 09:46:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

**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

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 17:28

PC Open Date & Time

08 SEP 2020 17:14

PC Close Date & Time

08 SEP 2020 19:44

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

**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 98.8 °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	09 SEP 2020 08:40
PC Open Date & Time	08 SEP 2020 20:39
PC Close Date & Time	09 SEP 2020 11:59

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:46:07

**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

98.5 °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

09 SEP 2020 22:37

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 15:52

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:46:07

**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

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:46:07

**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

99.1 °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

12 SEP 2020 23:51

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:46:07

**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

98.7 °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

14 SEP 2020 08:30

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

15 SEP 2020 08:11

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59



US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

**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

08 SEP 2020 17:28

PC Open Date & Time

08 SEP 2020 17:14

PC Close Date & Time

08 SEP 2020 19:44

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 08:41

PC Open Date & Time

08 SEP 2020 20:39

PC Close Date & Time

09 SEP 2020 11:59

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 22:38

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:46:07

**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

10 SEP 2020 15:53

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:46:07

**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

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:46:07

**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

12 SEP 2020 23:52

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:46:07

**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

14 SEP 2020 08:30

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:46:07

**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

15 SEP 2020 08:12

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59



US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

**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 ☐

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 17:29
PC Open Date & Time	08 SEP 2020 17:14
PC Close Date & Time	08 SEP 2020 19:44

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

**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 ☐

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 08:41
PC Open Date & Time	08 SEP 2020 20:39
PC Close Date & Time	09 SEP 2020 11:59

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:46:07

**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 ☒

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:46:07

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 22:38
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:46:07

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

94 of 1852

EAB) (1725)

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:46:07

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 15:53
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59



US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:46:07

Yes ☐

PC Time stamp

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:46:07

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:46:07

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 23:53
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:46:07

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 ☒

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:46:07

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 08:31
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:46:07

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 ☒

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:46:07

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 08:12
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59



US3772007

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Sep 2020 17:11:59

Generated On: 10 Jun 2021 09:46:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3772007

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Sep 2020 17:11:58

Generated On: 10 Jun 2021 09:46:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772007

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 20:34:04

Generated On: 10 Jun 2021 09:46:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3772007

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:34:04

Generated On: 10 Jun 2021 09:46:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772007

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 20:34:04

Generated On: 10 Jun 2021 09:46:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3772007

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:34:04

Generated On: 10 Jun 2021 09:46:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772007

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 20:34:04

Generated On: 10 Jun 2021 09:46:07

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3772007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 20:34:04

Generated On: 10 Jun 2021 09:46:07

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 OCT 2020
Time of assessment (00:00-23:59)	16:20 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 16:20
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3772007

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 20:34:04

Generated On: 10 Jun 2021 09:46:07

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.*

US3772007

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 20:34:04

Generated On: 10 Jun 2021 09:46:07

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 OCT 2020

Collection time (00:00-23:59)

16:30 (24 HR)

Collection date and time (derived)

12 OCT 2020 16:30

US3772007

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:34:04

Generated On: 10 Jun 2021 09:46:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

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"/>

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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

Date and time of submission

Patient Cloud Open Date & Time

05 OCT 2020 00:01

Patient Cloud Close Date & Time

09 OCT 2020 23:59

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 OCT 2020 16:22:43

Patient Cloud Open Date & Time

12 OCT 2020 00:01

Patient Cloud Close Date & Time

16 OCT 2020 23:59

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 OCT 2020 08:56:40

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 NOV 2020 18:01:54

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59



US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

TIMEPOINT	DAY 99
Have 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	10 NOV 2020 07:30:36
Patient Cloud Open Date & Time	09 NOV 2020 00:01
Patient Cloud Close Date & Time	13 NOV 2020 23:59

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

TIMEPOINT	DAY 106
Have you 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"/>

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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

Date and time of submission

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 NOV 2020 11:39:13

Patient Cloud Open Date & Time

20 NOV 2020 00:01

Patient Cloud Close Date & Time

24 NOV 2020 23:59

US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

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

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

27 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

01 DEC 2020 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 DEC 2020 09:53:17
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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

12 DEC 2020 20:48:44

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59



US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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

21 DEC 2020 20:13:51

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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

29 DEC 2020 11:09:47

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 JAN 2021 12:27:32
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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

11 JAN 2021 07:46:44

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

<b>TIMEPOINT</b>	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 JAN 2021 10:43:16
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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

22 JAN 2021 02:32:04

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 JAN 2021 08:10:28

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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

05 FEB 2021 08:26:00

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59



US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	13 FEB 2021 19:10:48
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 FEB 2021 11:59:11

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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

01 MAR 2021 12:44:34

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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

07 MAR 2021 15:14:07

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 MAR 2021 07:07:47

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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

19 MAR 2021 10:46:11

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 MAR 2021 15:51:44

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 APR 2021 00:15:15

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59



US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 11:55:21

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 10:10:22

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

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

Date and time of submission

23 APR 2021 11:24:04

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

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

Date and time of submission

30 APR 2021 08:59:37

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Close Date & Time](#)

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11 MAY 2021 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐  
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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Open Date & Time](#)

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14 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAY 2021 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

21 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

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="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"/>

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

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"/>

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Open Date & Time](#)

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09 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 JUL 2021 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

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

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Close Date & Time](#)

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27 JUL 2021 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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°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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Close Date & Time](#)

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10 AUG 2021 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	13 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 AUG 2021 23:59
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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

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

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

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Close Date & Time](#)

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31 AUG 2021 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Close Date & Time](#)

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07 SEP 2021 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

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

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 SEP 2021 23:59

US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐  
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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Open Date & Time](#)

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17 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 SEP 2021 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Close Date & Time](#)

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28 SEP 2021 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐ 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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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



US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	15 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 OCT 2021 23:59
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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐ 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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	22 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	26 OCT 2021 23:59
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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Open Date & Time](#)

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29 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 NOV 2021 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

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"/>

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

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

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

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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



US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Close Date & Time](#)

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07 DEC 2021 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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°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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	24 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	28 DEC 2021 23:59
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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Open Date & Time](#)

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31 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 JAN 2022 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Open Date & Time](#)

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14 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 JAN 2022 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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



US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Close Date & Time](#)

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01 FEB 2022 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Close Date & Time](#)

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08 FEB 2022 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Open Date & Time](#)

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11 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 FEB 2022 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Open Date & Time](#)

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11 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAR 2022 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Open Date & Time](#)

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18 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 MAR 2022 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

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"/>

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 MAR 2022 23:59

US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

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

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

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"/>

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Open Date & Time](#)

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08 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 APR 2022 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐  
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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59



US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Close Date & Time](#)

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26 APR 2022 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Open Date & Time](#)

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29 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 MAY 2022 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Open Date & Time](#)

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13 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAY 2022 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Open Date & Time](#)

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20 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAY 2022 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

27 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

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="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"/>

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Open Date & Time](#)

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17 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 JUN 2022 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

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"/>

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Open Date & Time](#)

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24 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 JUN 2022 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

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"/>

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

29 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Open Date & Time](#)

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05 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 AUG 2022 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

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

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	12 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2022 23:59
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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐  
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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Open Date & Time](#)

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19 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 AUG 2022 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Close Date & Time](#)

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30 AUG 2022 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

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US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 SEP 2022 23:59

US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**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 ☐

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59



US3772007

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

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"/>

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

---

07 OCT 2022 00:01

---

[Patient Cloud Close Date & Time](#)

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11 OCT 2022 23:59

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US3772007

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:46:07

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 12:44:42

US3772007

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 20:34:04

Generated On: 10 Jun 2021 09:46:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3772007

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:34:04

Generated On: 10 Jun 2021 09:46:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772007

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 20:33:59

Generated On: 10 Jun 2021 09:46:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3772007

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:33:59

Generated On: 10 Jun 2021 09:46:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772007

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 20:33:59

Generated On: 10 Jun 2021 09:46:07

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 04 JAN 2021

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

Comments

*If Contact Not Made, please provide Comments*



US3772007

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:33:59

Generated On: 10 Jun 2021 09:46:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772007

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 20:34:03

Generated On: 10 Jun 2021 09:46:07

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*

US3772007

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 20:34:03

Generated On: 10 Jun 2021 09:46:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772007

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 23 Mar 2021 02:51:15

Generated On: 10 Jun 2021 09:46:07

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 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

US3772007

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 02:29:48

Generated On: 10 Jun 2021 09:46:07

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) \_\_\_\_\_

US3772007

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Mar 2021 02:51:15

Generated On: 10 Jun 2021 09:46:07

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.*

US3772007

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Mar 2021 02:51:15

Generated On: 10 Jun 2021 09:46:07

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 MAR 2021

Collection time (00:00-23:59)

14:27 (24 HR)

Collection date and time (derived)

12 MAR 2021 14:27

US3772007

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 23 Mar 2021 02:51:15

Generated On: 10 Jun 2021 09:46:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3772007

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 15 Apr 2021 19:43:51

Generated On: 10 Jun 2021 09:46:07

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3772007

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 15 Apr 2021 19:43:51

Generated On: 10 Jun 2021 09:46:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3772007

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 03 May 2021 19:24:29

Generated On: 10 Jun 2021 09:46:07

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*

US3772007

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 03 May 2021 19:24:29

Generated On: 10 Jun 2021 09:46:07

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3772007**

**Folder: Safety Call Day 299 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:46:07**

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*

**US3772007**

**Folder: Safety Call Day 299 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:46:07**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3772007

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Data signed: (b) (4) 16 Sep 2020 17:11:58

Generated On: 10 Jun 2021 09:46:07

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

US3772007

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 16 Sep 2020 17:11:58

Generated On: 10 Jun 2021 09:46:07

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---



US3772007

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

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 20:33:59

Generated On: 10 Jun 2021 09:46:07

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

Visit date (dd MMM yyyy)	14 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3772007

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

Form: Unblinding

Data signed: (b) (4) 23 Mar 2021 02:51:15

Generated On: 10 Jun 2021 09:46:07

Date of updated informed consent ( <i>dd MMM yyyy</i> )	14 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	14 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	

US3772007

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 20:33:59

Generated On: 10 Jun 2021 09:46:07

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 JAN 2021

Collection time (00:00-23:59)

15:04 (24 HR)

Collection date and time (derived)

14 JAN 2021 15:04

US3772007

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Feb 2021 20:33:59

Generated On: 10 Jun 2021 09:46:07

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00 - 23:59)	15:06
Collection Date and Time (derived)	14 JAN 2021 15:06

US3772007

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Feb 2021 20:33:59

Generated On: 10 Jun 2021 09:46:07

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3772007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:07

AEID

Adverse event

DENTAL ABSCESS

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)

24 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)

30 SEP 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 ☐  
Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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US3772007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:07

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

US3772007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:07

AEID	USA-US107-2021-MRNA-1273-P30 1000009
Adverse event	LEFT BREAST DUCTAL CELL CARCINOMA
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)	05 FEB 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 type="radio"/> Grade 4 <input checked="" 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	True
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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US3772007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:07

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3772007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:07

SUBJECT CALLED SITE AND REPORTED BEING DIAGNOSED WITH BREAST CANCER ON 05 FEB 2021. THE SUBJECT STATED THEY HAVE NOT RECEIVED THE FINAL BIOPSY RESULTS TO INDICATE TYPE/ STAGE OF CANCER AND GRADING OF THE TUMOR. THE TUMOR IS A 3-5 CM MASS IN THE LEFT BREAST, THE SUBJECT DID GET THEIR LEFT ARM BUT RECEIVED PLACEBO AND OPTED NOT TO RECEIVE THE VACCINE. MEDICAL RECORDS HAVE BEEN REQUESTED FOR ADDITIONAL INFORMATION. RECEIPT OF PATHOLOGY REPORT INDICATES THIS IS INVASIVE DUCTAL CELL CARCINOMA IN THE LEFT BREAST. SUBJECT WILL BE SCHEDULING A DOUBLE MASTECTOMY. SUBJECT HAS NOT TAKEN ANY MEDICATION TO TREAT THIS SAE

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)	

US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 16 Feb 2021 20:33:59

Generated On: 10 Jun 2021 09:46:07

---

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

Yes ☒

No ☐

---

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

---

US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Mar 2021 02:51:15

Generated On: 10 Jun 2021 09:46:07

Name of Medication TRAMADOL

Prophylaxis Yes ☐  
No ☒

Indication DENTAL ABSCESS

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) 23 Mar 2021 02:51:15

Generated On: 10 Jun 2021 09:46:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 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) 6 OCT 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Mar 2021 02:51:15

Generated On: 10 Jun 2021 09:46:07

Name of Medication AUGMENTIN

Prophylaxis Yes ☐  
No ☒

Indication DENTAL ABSCESS

Dose per administration 875/125

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)

US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Mar 2021 02:51:15

Generated On: 10 Jun 2021 09:46:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 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)		6 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"/>

US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Mar 2021 02:51:15

Generated On: 10 Jun 2021 09:46:07

Name of Medication CHANTIX

Prophylaxis Yes ☐  
No ☒

Indication SMOKING CESSATION

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Mar 2021 02:51:15

Generated On: 10 Jun 2021 09:46:07

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3772007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Feb 2021 20:33:59

Generated On: 10 Jun 2021 09:46:07

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3772007

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 16 Sep 2020 17:11:58

Generated On: 10 Jun 2021 09:46:07

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

US3772007

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 16 Sep 2020 17:11:58

Generated On: 10 Jun 2021 09:46:07

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 ☐

US3772007

Folder: SAE USA-US107-2021-MRNA-1273-P301000009

Form: Safety Report Form

Data signed: (b) (4) 23 Apr 2021 22:44:38

Generated On: 10 Jun 2021 09:46:07

SAEID	USA-US107-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JAMSHID
Investigator's Last Name	SALEH
Site Address: Street	3652 EUREKA WAY
Site Address: City	REDDING
Site Address: State	
Site Address: Postal Code	96001
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3772007

Folder: SAE USA-US107-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Apr 2021 22:44:38

Generated On: 10 Jun 2021 09:46:07

SAEID	USA-US107-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JAMSHID
Investigator's Last Name	SALEH
Site Address: Street	3652 EUREKA WAY
Site Address: City	REDDING
Site Address: State	
Site Address: Postal Code	96001
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	16/FEB/2021 16:30
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

US3772007

Folder: SAE USA-US107-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Apr 2021 22:44:38

Generated On: 10 Jun 2021 09:46:07

SAEID	USA-US107-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JAMSHID
Investigator's Last Name	SALEH
Site Address: Street	3652 EUREKA WAY
Site Address: City	REDDING
Site Address: State	
Site Address: Postal Code	96001
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	15/MAR/2021 11:22
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

US3772007

Folder: SAE USA-US107-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Data signed: (b) (4) 23 Apr 2021 22:44:38

Generated On: 10 Jun 2021 09:46:07

SAEID	USA-US107-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JAMSHID
Investigator's Last Name	SALEH
Site Address: Street	3652 EUREKA WAY
Site Address: City	REDDING
Site Address: State	
Site Address: Postal Code	96001
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	30/MAR/2021 15:12
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



US3772007

Folder: SAE USA-US107-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Data signed: (b) (4) 23 Apr 2021 22:44:38

Generated On: 10 Jun 2021 09:46:07

SAEID	USA-US107-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JAMSHID
Investigator's Last Name	SALEH
Site Address: Street	3652 EUREKA WAY
Site Address: City	REDDING
Site Address: State	
Site Address: Postal Code	96001
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	16/APR/2021 11:55
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

US3772007 (Prod: Paradigm Clinical Research Institute Inc - ClinEdge - PPDS)

**US3772007**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:46:07**

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:35:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'US3772007'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 15:29:58

US3772007

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:46:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:01
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Aug 2020 16:20:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Aug 2020 16:20:42
User entered 'Yes (Y)' reason for change: New Information	Sarah Sandberg (b) (4)	05 Aug 2020 16:20:42
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Aug 2020 16:20:38
User entered empty.	System	05 Aug 2020 16:20:38
	Sarah Sandberg (b) (4)	05 Aug 2020 16:20:38
	(b) (4)	

US3772007

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:01
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '05 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 15:29:59

US3772007

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:01
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Clinic (Clinic)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Aug 2020 16:20:38

US3772007

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:46:07

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
User entered 'SCRN'	System	05 Aug 2020 16:20:42
User entered empty.	System	05 Aug 2020 16:20:38

US3772007

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:46:07

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:05
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered (b) (6) 1986'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 15:29:59



US3772007

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:46:07

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:05
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '33'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Aug 2020 16:21:04

**US3772007**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:46:07**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
User entered 'YEARS'	System	05 Aug 2020 16:21:04

US3772007

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:46:07

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
User entered '33'	System	05 Aug 2020 16:21:27

**US3772007**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:46:07**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:05
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Female (F)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Aug 2020 16:21:04

US3772007

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:46:07

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:05
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Aug 2020 16:21:04

US3772007

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:46:07

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:05
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'I'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Aug 2020 16:21:04

US3772007

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:46:07

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:05
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '0'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Aug 2020 16:21:04

**US3772007**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:46:07**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:05
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '0'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Aug 2020 16:21:04



US3772007

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:46:07

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:05
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '0'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Aug 2020 16:21:04

US3772007

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:46:07

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:05
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '0'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Aug 2020 16:21:04

US3772007

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:46:07

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:05
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '0'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Aug 2020 16:21:04

US3772007

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:46:07

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:05
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered empty.	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Aug 2020 16:21:04

US3772007

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:46:07

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:05
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '0'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Aug 2020 16:21:04

**US3772007**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:46:07**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:05
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '0'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Aug 2020 16:21:04

US3772007

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:46:07

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:07
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '05 Aug 2020'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Aug 2020 16:21:27

US3772007

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
User entered 'Aug 2020'	System	05 Aug 2020 16:21:27



US3772007

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
User entered '2020'	System	05 Aug 2020 16:21:27

**US3772007**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:46:07**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:07
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Amendment 1 (1)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Aug 2020 16:21:27

US3772007

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:07
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Yes (Y)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Aug 2020 16:21:27

US3772007

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:46:07

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:07
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered empty.	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Aug 2020 16:21:27

US3772007

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:46:07

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:07
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered empty.	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Aug 2020 16:21:27

**US3772007**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:46:07**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:07
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'No (N)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Aug 2020 16:21:27

US3772007

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:46:07

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:07
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 15:29:59

US3772007

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:46:07

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
User entered 'I'	System	05 Aug 2020 16:21:50



US3772007

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:13
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Yes (Y)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Aug 2020 16:21:50

US3772007

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:46:07

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:15
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Yes (Y)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Aug 2020 16:22:22

US3772007

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:46:07

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:20
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Fallopian tube therapeutic procedures, PT: Salpingectomy, LLT: Salpingectomy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	05 Aug 2020 17:15:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 17:15:02
Data point term sent to Coder	System	05 Aug 2020 17:13:30
User entered 'Bilateral Salpingectomy'	Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:13:15

US3772007

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:20
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'un UNK 2013'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:13:15

**US3772007**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:46:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:20
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:13:15

**US3772007**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:46:07**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:20
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:13:15

**US3772007**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:46:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:20
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'un UNK 2013'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:13:15

**US3772007**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:46:07**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:20
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:13:15



**US3772007**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:46:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
User entered 'Jan 2013'	System	05 Aug 2020 17:13:15

**US3772007**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:46:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
User entered '2013'	System	05 Aug 2020 17:13:15

US3772007

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
User entered 'Jan 2013'	System	05 Aug 2020 17:13:15

**US3772007**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:46:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
User entered '2013'	System	05 Aug 2020 17:13:15

US3772007

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:46:07

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:20
User closed query 'Per MM, please expand the abbreviation ' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 12:49:36
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: Cesarean section - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 15:42:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	15 Sep 2020 15:42:41
Data point term sent to Coder	System	15 Sep 2020 15:41:21
Query 'Per MM, please expand the abbreviation ' answered with 'updated' (Site from DM).	Emily Crews (b) (4)	15 Sep 2020 15:41:17
Coding entries removed.	(b) (4)	15 Sep 2020 15:41:17
User entered 'Cesarean Section' reason for change: Data Entry Error	Emily Crews (b) (4)	15 Sep 2020 15:41:08
User opened query 'Per MM, please expand the abbreviation ' (Site from DM).	(b) (4)	15 Sep 2020 15:41:08
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: C-section - version MedDRA\\23.0.	(b) (4), (b) (6)	11 Sep 2020 23:26:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 17:15:04
Data point term sent to Coder	(b) (4)	05 Aug 2020 17:15:04
User entered 'C-Section'	System	05 Aug 2020 17:14:31
	Emily Crews (b) (4)	05 Aug 2020 17:14:15
	(b) (4)	

US3772007

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:20
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'un UNK 2007'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:14:15

**US3772007**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:46:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:20
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:14:15

US3772007

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:46:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:20
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:14:15



**US3772007**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:46:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:20
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'un UNK 2007'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:14:15

**US3772007**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:46:07**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:20
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:14:15

**US3772007**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:46:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
User entered 'Jan 2007'	System	05 Aug 2020 17:14:15

**US3772007**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:46:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
User entered '2007'	System	05 Aug 2020 17:14:15

**US3772007**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:46:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
User entered 'Jan 2007'	System	05 Aug 2020 17:14:15

**US3772007**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:46:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
User entered '2007'	System	05 Aug 2020 17:14:15

US3772007

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:46:07

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:20
User closed query 'Per MM, please expand the abbreviation ' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 12:50:05
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: Cesarean section - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	15 Sep 2020 15:43:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 15:43:40
Data point term sent to Coder	System	15 Sep 2020 15:42:21
Query 'Per MM, please expand the abbreviation ' answered with 'updated' (Site from DM).	Emily Crews (b) (4) (b) (4)	15 Sep 2020 15:41:46
Coding entries removed.	Emily Crews (b) (4) (b) (4)	15 Sep 2020 15:41:40
User entered 'Cesarean Section' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	15 Sep 2020 15:41:40
User opened query 'Per MM, please expand the abbreviation ' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 23:26:53
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: C-section - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 17:17:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 17:17:01
Data point term sent to Coder	System	05 Aug 2020 17:15:32
User entered 'C-Section'	Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:14:38

US3772007

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:20
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'un UNK 2011'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:14:38



**US3772007**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:46:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:20
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:14:38

US3772007

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:46:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:20
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:14:38

**US3772007**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:46:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:20
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'un UNK 2011'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:14:38

**US3772007**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:46:07**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:20
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:14:38

US3772007

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:46:07

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
User entered 'Jan 2011'	System	05 Aug 2020 17:14:38

**US3772007**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:46:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
User entered '2011'	System	05 Aug 2020 17:14:38

**US3772007**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:46:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
User entered 'Jan 2011'	System	05 Aug 2020 17:14:38

**US3772007**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:46:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
User entered '2011'	System	05 Aug 2020 17:14:38



US3772007

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:46:07

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:20
User signature succeeded.	Jamshid Saleh (b) (4)	31 Mar 2021 19:29:24
User coded data point as SOC: Psychiatric disorders, HLGT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Nicotine dependence, LLT: Nicotine addiction - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	31 Mar 2021 08:05:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Mar 2021 08:05:31
Data point term sent to Coder	System	30 Mar 2021 17:09:45
User entered 'Nicotine Addiction (1 pack per Day)'	Emily Crews (b) (4) (b) (4)	30 Mar 2021 17:09:41

**US3772007**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:46:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:20
User signature succeeded.	Jamshid Saleh (b) (4)	31 Mar 2021 19:29:24
User entered 'un UNK 2006'	(b) (4) Emily Crews (b) (4) (b) (4)	30 Mar 2021 17:09:41

**US3772007**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:46:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:20
User signature succeeded.	Jamshid Saleh (b) (4)	31 Mar 2021 19:29:24
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	30 Mar 2021 17:09:41

US3772007

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:46:07

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:20
User signature succeeded.	Jamshid Saleh (b) (4)	31 Mar 2021 19:29:24
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	30 Mar 2021 17:09:41

**US3772007**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:46:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:20
User signature succeeded.	Jamshid Saleh (b) (4)	31 Mar 2021 19:29:24
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	30 Mar 2021 17:09:41

**US3772007**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:46:07**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:20
User signature succeeded.	Jamshid Saleh (b) (4)	31 Mar 2021 19:29:24
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	30 Mar 2021 17:09:41

US3772007

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:46:07

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
User entered 'Jan 2006'	System	30 Mar 2021 17:09:41

**US3772007**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:46:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
User entered '2006'	System	30 Mar 2021 17:09:41



**US3772007**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:46:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
User entered empty.	System	30 Mar 2021 17:09:41

**US3772007**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:46:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
User entered empty.	System	30 Mar 2021 17:09:41

US3772007

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:16:09

US3772007

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '05 Aug 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:16:09

US3772007

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '08:40'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:16:09

**US3772007**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:46:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
User entered '05 Aug 2020 08:40'	System	05 Aug 2020 17:16:09

US3772007

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '156' cm	(b) (4) Emily Crews (b) (4)	05 Aug 2020 17:16:09
DataPoint set to visible.	(b) (4) System	05 Aug 2020 16:21:50

US3772007

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '42.3' kg	(b) (4) Emily Crews (b) (4)	05 Aug 2020 17:16:09
DataPoint set to visible.	(b) (4) System	05 Aug 2020 16:21:50



US3772007

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
Amendment Manager: User entered '17.38166'	System	16 Sep 2020 23:43:56
User entered '17.4'	System	05 Aug 2020 17:16:09
DataPoint set to visible.	System	05 Aug 2020 16:21:50

US3772007

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
User entered 'kg/m2'	System	05 Aug 2020 17:16:09
DataPoint set to visible.	System	05 Aug 2020 16:21:50

US3772007

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User closed query 'Per CDM: As per per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Sep 2020 19:15:58
Query 'Per CDM: As per per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' answered with 'updated' (Site from DM).	Emily Crews (b) (4) (b) (4)	15 Sep 2020 15:43:14
User entered missing code ND - Not Done; reason for change Data Entry Error	Emily Crews (b) (4) (b) (4)	15 Sep 2020 15:43:08
User opened query 'Per CDM: As per per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 11:01:46
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	05 Aug 2020 17:16:15
User entered '36.5' C reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:16:15
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	05 Aug 2020 17:16:09
User entered '36.5' (non-conformant).	Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:16:09

US3772007

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered empty; reason for change Data Entry Error	(b) (4)	
	Emily Crews (b) (4)	15 Sep 2020 15:43:08
User entered 'Oral (Oral)'	(b) (4)	
	Emily Crews (b) (4)	05 Aug 2020 17:16:09
	(b) (4)	

US3772007

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:16:09

US3772007

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Sep 2020 15:43:08
User entered '72'	Emily Crews (b) (4)	05 Aug 2020 17:16:09
	(b) (4)	

**US3772007**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:46:07**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
User entered 'bpm'	System	05 Aug 2020 17:16:09

US3772007

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Sep 2020 15:43:08
User entered '12'	Emily Crews (b) (4)	05 Aug 2020 17:16:09
	(b) (4)	



US3772007

Folder: Screening

Form: Vital Signs

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[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
User entered 'breaths/min'	System	05 Aug 2020 17:16:09

US3772007

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Sep 2020 15:43:08
User entered '90'	Emily Crews (b) (4)	05 Aug 2020 17:16:09
	(b) (4)	

US3772007

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
User entered 'mmHg'	System	05 Aug 2020 17:16:09

US3772007

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:26
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Sep 2020 15:43:08
User entered '70'	Emily Crews (b) (4)	05 Aug 2020 17:16:09
	(b) (4)	

US3772007

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
User entered 'mmHg'	System	05 Aug 2020 17:16:09

US3772007

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 07:20:10

US3772007

Folder: Screening

Form: Vital Signs

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Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 07:20:10

US3772007

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:46:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:30
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:18:44



US3772007

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:46:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:30
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 14:58:54
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		09 Sep 2020 00:19:24
User entered '05 Aug 2020'	Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:18:44

US3772007

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:46:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:33
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '05 Aug 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:19:32

US3772007

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:46:07

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:33
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:19:32

US3772007

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:46:07

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:33
User closed query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 13:52:57
Query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' answered with 'Bilateral Salpingectomy is documented in medical history' (Site from DM).	Emily Crews (b) (4) (b) (4)	06 Oct 2020 20:54:26
User opened query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:48:50
User signature succeeded.	Jamshid Saleh (b) (4) (b) (4)	16 Sep 2020 17:12:00
User entered 'Surgically sterile (SURGICALLY STERILE)'	Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:19:32

US3772007

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:46:07

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:33
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:19:32

US3772007

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:46:07

If Surgically sterile, date of surgery (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:33
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'un UNK 2013'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:19:32

US3772007

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:46:07

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:33
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:19:32

US3772007

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:46:07

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:33
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:19:32



US3772007

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:46:07

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:04
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:33
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:19:32

US3772007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:46:07

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:37
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:20:59

US3772007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:46:07

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:37
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:20:59

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:46:07

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:37
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:20:59

US3772007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:46:07

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:37
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:20:59

US3772007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:46:07

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:37
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:20:59

US3772007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:46:07

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:37
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:20:59

US3772007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:46:07

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:37
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:20:59



US3772007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:46:07

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:37
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:20:59

US3772007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:46:07

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:37
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:20:59

US3772007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:46:07

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:37
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:20:59

US3772007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:46:07

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:37
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:20:59

US3772007

Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:37
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:20:59

US3772007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:46:07

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:37
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:20:59

US3772007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:46:07

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:20:59

US3772007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:37
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:20:59



US3772007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:46:07

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:37
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:20:59

US3772007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:46:07

**Resides in high density housing** (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:37
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:20:59

US3772007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:46:07

**Resides in low density, multi-family setting without** (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:37
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:20:59

US3772007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:46:07

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:37
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'I'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:20:59

US3772007

Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:20:59

US3772007

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:46:07

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:09:37
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 17:20:59

US3772007

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:46:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Yes (Y)'	Sarah Sandberg (b) (4)	05 Aug 2020 16:42:13

US3772007

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:46:07

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '05 Aug 2020'	Sarah Sandberg (b) (4)	05 Aug 2020 16:42:13



US3772007

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Clinic (Clinic)'	Sarah Sandberg (b) (4)	05 Aug 2020 16:42:13

**US3772007**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:46:07**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered 'VISIT1'	System	05 Aug 2020 16:42:13

US3772007

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '05 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 16:04:41

US3772007

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:46:07

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 02:14:19
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:14:19
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	05 Aug 2020 16:04:41
User entered '101130' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 16:04:41

US3772007

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:46:07

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 16:04:41

US3772007

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:46:07

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)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'No (N)'	Sarah Sandberg (b) (4)	05 Aug 2020 16:52:01

US3772007

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:46:07

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)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'No (N)'	Sarah Sandberg (b) (4)	05 Aug 2020 16:52:01

US3772007

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:46:07

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'No (N)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Aug 2020 16:52:01



**US3772007**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:46:07**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'No (N)'	(b) (4) Sarah Sandberg (b) (4)	05 Aug 2020 16:52:01

US3772007

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:46:07

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'No (N)'	(b) (4) Sarah Sandberg (b) (4)	05 Aug 2020 16:52:01

US3772007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:46:07

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User closed query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT since participant is screened, enrolled, randomized, and dose on the same day. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:37:57
Query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT since participant is screened, enrolled, randomized, and dose on the same day. Please update accordingly.' answered with 'updated' (Site from DM).	Emily Crews (b) (4) (b) (4)	15 Sep 2020 15:43:46
User entered missing code ND - Not Done; reason for change Data Entry Error	Emily Crews (b) (4) (b) (4)	15 Sep 2020 15:43:40
User opened query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT since participant is screened, enrolled, randomized, and dose on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 11:02:16
User entered '156' cm	Sarah Sandberg (b) (4) (b) (4)	05 Aug 2020 16:51:50

US3772007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:46:07

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Sep 2020 15:43:40
User entered '42.3' kg	Emily Crews (b) (4)	15 Sep 2020 15:43:40
	(b) (4)	
	Sarah Sandberg (b) (4)	05 Aug 2020 16:51:50
	(b) (4)	

US3772007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:46:07

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User closed query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT since participant is screened, enrolled, randomized, and dose on the same day. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:37:57
Query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT since participant is screened, enrolled, randomized, and dose on the same day. Please update accordingly.' answered with 'updated' (Site from DM).	Emily Crews (b) (4) (b) (4)	15 Sep 2020 15:43:46
User entered missing code ND - Not Done; reason for change Data Entry Error	Emily Crews (b) (4) (b) (4)	15 Sep 2020 15:43:40
User opened query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT since participant is screened, enrolled, randomized, and dose on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 11:02:16
User entered '156' cm	Sarah Sandberg (b) (4) (b) (4)	05 Aug 2020 16:51:50

US3772007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:46:07

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Sep 2020 15:43:40
User entered '42.3' kg	Emily Crews (b) (4)	15 Sep 2020 15:43:40
	(b) (4)	
	Sarah Sandberg (b) (4)	05 Aug 2020 16:51:50
	(b) (4)	

US3772007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User accepted default value 'Pre-Dose (PREDOSE)'	Sarah Sandberg (b) (4) (b) (4)	05 Aug 2020 16:51:50

US3772007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Yes (Y)'	(b) (4) Sarah Sandberg (b) (4)	05 Aug 2020 16:51:50



US3772007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '05 Aug 2020'	(b) (4) Sarah Sandberg (b) (4)	05 Aug 2020 16:51:50

US3772007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '08:40'	(b) (4) Sarah Sandberg (b) (4)	05 Aug 2020 16:51:50

US3772007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered '05 Aug 2020 08:40'	System	05 Aug 2020 16:51:50

US3772007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '36.5' C	Sarah Sandberg (b) (4)	05 Aug 2020 16:51:50

US3772007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Oral (Oral)'	(b) (4) Sarah Sandberg (b) (4)	05 Aug 2020 16:51:50

US3772007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	05 Aug 2020 16:51:50

US3772007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '72'	(b) (4) Sarah Sandberg (b) (4)	05 Aug 2020 16:51:50

US3772007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered 'bpm'	System	05 Aug 2020 16:51:50



US3772007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '12'	(b) (4) Sarah Sandberg (b) (4)	05 Aug 2020 16:51:50

US3772007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered 'breaths/min'	System	05 Aug 2020 16:51:50

US3772007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '90'	Sarah Sandberg (b) (4)	05 Aug 2020 16:51:50

US3772007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered 'mmHg'	System	05 Aug 2020 16:51:50

US3772007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '70'	Sarah Sandberg (b) (4)	05 Aug 2020 16:51:50

US3772007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered 'mmHg'	System	05 Aug 2020 16:51:50

US3772007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:46:07

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User closed query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT since participant is screened, enrolled, randomized, and dose on the same day. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 16:37:57
Query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT since participant is screened, enrolled, randomized, and dose on the same day. Please update accordingly.' answered with 'updated' (Site from DM).	Emily Crews (b) (4) (b) (4)	15 Sep 2020 15:43:46
User entered missing code ND - Not Done; reason for change Data Entry Error	Emily Crews (b) (4) (b) (4)	15 Sep 2020 15:43:40
User opened query 'Per CDM: As per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT since participant is screened, enrolled, randomized, and dose on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 11:02:16
User entered '156' cm	Sarah Sandberg (b) (4) (b) (4)	05 Aug 2020 16:51:50

US3772007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:46:07

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	15 Sep 2020 15:43:40
User entered '42.3' kg	Emily Crews (b) (4)	15 Sep 2020 15:43:40
	(b) (4)	
	Sarah Sandberg (b) (4)	05 Aug 2020 16:51:50
	(b) (4)	



US3772007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User accepted default value 'Post-Dose (POSTDOSE)'	Sarah Sandberg (b) (4) (b) (4)	05 Aug 2020 16:51:50

US3772007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Aug 2020 23:37:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Aug 2020 23:37:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Emily Crews (b) (4)	05 Aug 2020 23:37:59
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	05 Aug 2020 16:51:50
User entered empty.	System	05 Aug 2020 16:51:50
	Sarah Sandberg (b) (4)	05 Aug 2020 16:51:50
	(b) (4)	

US3772007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '05 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Emily Crews (b) (4)	05 Aug 2020 23:37:59
User entered empty.	(b) (4)	
	Sarah Sandberg (b) (4)	05 Aug 2020 16:51:50
	(b) (4)	

US3772007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	07 Aug 2020 05:08:58
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'correct as is per protocol ' (Site from System).	Emily Crews (b) (4) (b) (4)	05 Aug 2020 23:38:52
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		05 Aug 2020 23:37:59
User entered '09:57' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	05 Aug 2020 23:37:59
User entered empty.	Sarah Sandberg (b) (4) (b) (4)	05 Aug 2020 16:51:50

US3772007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered '05 Aug 2020 09:57'	System	05 Aug 2020 23:37:59
User entered empty.	System	05 Aug 2020 16:51:50

US3772007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '37.4' C reason for change: Data Entry Error	(b) (4)	
	Emily Crews (b) (4)	05 Aug 2020 23:37:59
User entered empty.	(b) (4)	
	Sarah Sandberg (b) (4)	05 Aug 2020 16:51:50
	(b) (4)	

US3772007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	
	Emily Crews (b) (4)	05 Aug 2020 23:37:59
User entered empty.	(b) (4)	
	Sarah Sandberg (b) (4)	05 Aug 2020 16:51:50
	(b) (4)	

US3772007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	05 Aug 2020 16:51:50



US3772007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '63' reason for change: Data Entry Error	(b) (4)	
	Emily Crews (b) (4)	05 Aug 2020 23:37:59
User entered empty.	(b) (4)	
	Sarah Sandberg (b) (4)	05 Aug 2020 16:51:50
	(b) (4)	

US3772007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered 'bpm'	System	05 Aug 2020 23:37:59
User entered empty.	System	05 Aug 2020 16:51:50

US3772007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '14' reason for change: Data Entry Error	(b) (4) Emily Crews (b) (4)	05 Aug 2020 23:37:59
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	05 Aug 2020 16:51:50
	(b) (4)	

US3772007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered 'breaths/min'	System	05 Aug 2020 23:37:59
User entered empty.	System	05 Aug 2020 16:51:50

US3772007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '110' reason for change: Data Entry Error	(b) (4)	
	Emily Crews (b) (4)	05 Aug 2020 23:37:59
User entered empty.	(b) (4)	
	Sarah Sandberg (b) (4)	05 Aug 2020 16:51:50
	(b) (4)	

US3772007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered 'mmHg'	System	05 Aug 2020 23:37:59
User entered empty.	System	05 Aug 2020 16:51:50

US3772007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:07

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '70' reason for change: Data Entry Error	(b) (4)	
	Emily Crews (b) (4)	05 Aug 2020 23:37:59
User entered empty.	(b) (4)	
	Sarah Sandberg (b) (4)	05 Aug 2020 16:51:50
	(b) (4)	

US3772007

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered 'mmHg'	System	05 Aug 2020 23:37:59
User entered empty.	System	05 Aug 2020 16:51:50



US3772007

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:46:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Yes (Y)'	(b) (4) Sarah Sandberg (b) (4)	05 Aug 2020 16:48:36

US3772007

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:46:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	05 Aug 2020 16:48:42
User closed query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	05 Aug 2020 16:48:42
User entered '05 Aug 2020' reason for change: Data Entry Error	Sarah Sandberg (b) (4)	05 Aug 2020 16:48:42
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	05 Aug 2020 16:48:36
User opened query 'The physical examination date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	05 Aug 2020 16:48:36
User entered '04 Aug 2020'	Sarah Sandberg (b) (4)	05 Aug 2020 16:48:36

US3772007

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:46:07

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Yes (Y)'	(b) (4) Sarah Sandberg (b) (4)	05 Aug 2020 16:41:51

US3772007

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:46:07

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	05 Aug 2020 16:41:51

US3772007

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered empty.	Sarah Sandberg (b) (4)	05 Aug 2020 16:41:51

US3772007

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:46:07

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered 'MRNA-1273 OR PLACEBO'	System	05 Aug 2020 16:41:51

US3772007

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:46:07

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '05 Aug 2020'	Sarah Sandberg (b) (4)	05 Aug 2020 16:41:51

US3772007

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:46:07

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '09:22'	Sarah Sandberg (b) (4)	05 Aug 2020 16:41:51



US3772007

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:46:07

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered '05 Aug 2020 09:22'	System	05 Aug 2020 16:41:51

US3772007

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:46:07

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Left Arm (LEFT ARM)'	Sarah Sandberg (b) (4)	05 Aug 2020 16:41:51

US3772007

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:46:07

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered 'ONCE'	System	05 Aug 2020 16:41:51

US3772007

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:46:07

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered 'INTRAMUSCULAR'	System	05 Aug 2020 16:41:51

US3772007

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:46:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Yes (Y)'	Sarah Sandberg (b) (4)	05 Aug 2020 16:23:49

US3772007

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:46:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '05 Aug 2020'	Sarah Sandberg (b) (4)	05 Aug 2020 16:23:49

**US3772007**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:46:07**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '09:07'	Sarah Sandberg (b) (4)	05 Aug 2020 16:23:49

**US3772007**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:46:07**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered '05 Aug 2020 09:07'	System	05 Aug 2020 16:23:49



US3772007

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:46:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '05 Aug 2020'	(b) (4) Sarah Sandberg (b) (4)	05 Aug 2020 16:24:06

US3772007

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:46:07

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Sarah Sandberg (b) (4) (b) (4)	05 Aug 2020 16:24:06

US3772007

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:46:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Yes (Y)'	(b) (4) Sarah Sandberg (b) (4)	05 Aug 2020 16:24:06

US3772007

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:46:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '09:12'	(b) (4) Sarah Sandberg (b) (4)	05 Aug 2020 16:24:06

**US3772007**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:46:07**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered '05 Aug 2020 09:12'	System	05 Aug 2020 16:24:06

US3772007

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:46:07

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Sarah Sandberg (b) (4) (b) (4)	05 Aug 2020 16:24:06

US3772007

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:46:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'No (N)'	(b) (4) Sarah Sandberg (b) (4)	05 Aug 2020 16:24:06

US3772007

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:46:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	05 Aug 2020 16:24:06



**US3772007**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:46:07**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered empty.	System	05 Aug 2020 16:24:06

US3772007

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:46:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Yes (Y)'	(b) (4) Sarah Sandberg (b) (4)	05 Aug 2020 16:24:11

**US3772007**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:46:07**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered 'I'	System	05 Aug 2020 16:24:11

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	05 Aug 2020 16:41:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-05T09:59:07', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '9a5c3dca-2499-40a3-856c-9d1ba164b37a'	System	05 Aug 2020 16:59:52
User entered 'Yes (Y)'	System	05 Aug 2020 16:59:52

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-05T09:59:38', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '9a5c3dca-2499-40a3-856c-9d1ba164b37a'	System	05 Aug 2020 16:59:52
User entered '99.3'	System	05 Aug 2020 16:59:52

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-05T09:59:41', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '9a5c3dca-2499-40a3-856c-9d1ba164b37a'	System	05 Aug 2020 16:59:52
User entered 'No (N)'	System	05 Aug 2020 16:59:52

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-05T09:59:49', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '9a5c3dca-2499-40a3-856c-9d1ba164b37a'	System	05 Aug 2020 16:59:52
User entered '05 Aug 2020 09:59'	System	05 Aug 2020 16:59:52



US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '05 Aug 2020 09:42'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '05 Aug 2020 12:12'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	05 Aug 2020 16:41:51
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-05T21:00:59', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'c08c93fc-cc9d-42bc-af2e-6696b567477f'	System	06 Aug 2020 04:01:15
User entered 'Yes (Y)'	System	06 Aug 2020 04:01:15

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-05T21:01:04', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'c08c93fc-cc9d-42bc-af2e-6696b567477f'	System	06 Aug 2020 04:01:15
User entered '99.4'	System	06 Aug 2020 04:01:15

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-05T21:01:07', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'c08c93fc-cc9d-42bc-af2e-6696b567477f'	System	06 Aug 2020 04:01:15
User entered 'No (N)'	System	06 Aug 2020 04:01:15

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-05T21:01:12', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'c08c93fc-cc9d-42bc-af2e-6696b567477f'	System	06 Aug 2020 04:01:15
User entered '05 Aug 2020 21:01'	System	06 Aug 2020 04:01:15

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '05 Aug 2020 13:07'	System	05 Aug 2020 16:41:51



US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	05 Aug 2020 16:41:51
User entered 'Day 2'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:46:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-06T13:59:34', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '49cddffe-fced-414f-a15e-a842d58acd68'	System	06 Aug 2020 20:59:47
User entered 'Yes (Y)'	System	06 Aug 2020 20:59:47

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:46:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-06T13:59:39', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '49cddffe-fced-414f-a15e-a842d58acd68'	System	06 Aug 2020 20:59:47
User entered '98.8'	System	06 Aug 2020 20:59:47

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-06T13:59:41', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '49cddffe-fced-414f-a15e-a842d58acd68'	System	06 Aug 2020 20:59:47
User entered 'No (N)'	System	06 Aug 2020 20:59:47

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:46:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-06T13:59:45', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '49cddffe-fced-414f-a15e-a842d58acd68'	System	06 Aug 2020 20:59:47
User entered '06 Aug 2020 13:59'	System	06 Aug 2020 20:59:47

**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:46:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 16:41:51



US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	05 Aug 2020 16:41:51
User entered 'Day 3'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:46:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-07T15:39:12', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'd6bfc282-d6ea-4eb6-bfe1-e78eba0d311a'	System	07 Aug 2020 22:39:27
User entered 'Yes (Y)'	System	07 Aug 2020 22:39:27

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:46:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-07T15:39:16', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'd6bfc282-d6ea-4eb6-bfe1-e78eba0d311a'	System	07 Aug 2020 22:39:27
User entered '98.7'	System	07 Aug 2020 22:39:27

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-07T15:39:19', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'd6bfc282-d6ea-4eb6-bfe1-e78eba0d311a'	System	07 Aug 2020 22:39:27
User entered 'No (N)'	System	07 Aug 2020 22:39:27

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:46:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-07T15:39:24', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'd6bfc282-d6ea-4eb6-bfe1-e78eba0d311a'	System	07 Aug 2020 22:39:27
User entered '07 Aug 2020 15:39'	System	07 Aug 2020 22:39:27

**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 16:41:51

**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	05 Aug 2020 16:41:51
User entered 'Day 4'	System	05 Aug 2020 16:41:51



US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:46:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-08T12:10:19', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'e6951c10-b112-4663-b250-c41c49b50fab'	System	09 Aug 2020 00:07:45
User entered 'Yes (Y)'	System	09 Aug 2020 00:07:45

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:46:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-08T12:10:24', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'e6951c10-b112-4663-b250-c41c49b50fab'	System	09 Aug 2020 00:07:45
User entered '98.3'	System	09 Aug 2020 00:07:45

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-08T12:10:26', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'e6951c10-b112-4663-b250-c41c49b50fab'	System	09 Aug 2020 00:07:45
User entered 'No (N)'	System	09 Aug 2020 00:07:45

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:46:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-08T12:10:29', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'e6951c10-b112-4663-b250-c41c49b50fab'	System	09 Aug 2020 00:07:45
User entered '08 Aug 2020 12:10'	System	09 Aug 2020 00:07:45

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:46:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:46:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	05 Aug 2020 16:41:51
User entered 'Day 5'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:46:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-09T17:14:25', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'b766f3f8-7cd7-40f4-82e3-9eb80bd4466a'	System	10 Aug 2020 00:14:38
User entered 'Yes (Y)'	System	10 Aug 2020 00:14:38



US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:46:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-09T17:14:30', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'b766f3f8-7cd7-40f4-82e3-9eb80bd4466a'	System	10 Aug 2020 00:14:38
User entered '98.6'	System	10 Aug 2020 00:14:38

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-09T17:14:33', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'b766f3f8-7cd7-40f4-82e3-9eb80bd4466a'	System	10 Aug 2020 00:14:38
User entered 'No (N)'	System	10 Aug 2020 00:14:38

**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-09T17:14:36', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'b766f3f8-7cd7-40f4-82e3-9eb80bd4466a'	System	10 Aug 2020 00:14:38
User entered '09 Aug 2020 17:14'	System	10 Aug 2020 00:14:38

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:46:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:46:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	05 Aug 2020 16:41:51
User entered 'Day 6'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:46:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-11T09:07:52', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '3022ccb5-5712-480b-86b3-c25e46a137c4'	System	11 Aug 2020 16:08:00
User entered 'Yes (Y)'	System	11 Aug 2020 16:08:00

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:46:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-11T09:07:47', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '3022ccb5-5712-480b-86b3-c25e46a137c4'	System	11 Aug 2020 16:08:00
User entered '98.4'	System	11 Aug 2020 16:08:00



US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-11T09:07:49', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '3022ccb5-5712-480b-86b3-c25e46a137c4'	System	11 Aug 2020 16:08:00
User entered 'No (N)'	System	11 Aug 2020 16:08:00

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:46:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-11T09:07:54', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '3022ccb5-5712-480b-86b3-c25e46a137c4'	System	11 Aug 2020 16:08:00
User entered '11 Aug 2020 09:07'	System	11 Aug 2020 16:08:00

**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 16:41:51

**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	05 Aug 2020 16:41:51
User entered 'Day 7'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:46:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-12T08:44:13', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'adc40e4c-88d0-47dc-bebc-685326e8ef5e'	System	12 Aug 2020 15:44:28
User entered 'Yes (Y)'	System	12 Aug 2020 15:44:28

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:46:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-12T08:44:18', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'adc40e4c-88d0-47dc-bebc-685326e8ef5e'	System	12 Aug 2020 15:44:28
User entered '98.4'	System	12 Aug 2020 15:44:28

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-12T08:44:22', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'adc40e4c-88d0-47dc-bebc-685326e8ef5e'	System	12 Aug 2020 15:44:28
User entered 'No (N)'	System	12 Aug 2020 15:44:28



US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:46:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-12T08:44:25', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'adc40e4c-88d0-47dc-bebc-685326e8ef5e'	System	12 Aug 2020 15:44:28
User entered '12 Aug 2020 08:44'	System	12 Aug 2020 15:44:28

US3772007

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:46:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 16:41:51

**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	05 Aug 2020 16:41:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-05T09:59:56', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'd2e42245-0125-44ef-8cb9-5e1f55335fe7'	System	05 Aug 2020 17:00:21
User entered 'None (1)'	System	05 Aug 2020 17:00:21

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-05T10:00:09', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'd2e42245-0125-44ef-8cb9-5e1f55335fe7'	System	05 Aug 2020 17:00:21
User entered 'No (N)'	System	05 Aug 2020 17:00:21

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-05T10:00:11', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'd2e42245-0125-44ef-8cb9-5e1f55335fe7'	System	05 Aug 2020 17:00:21
User entered 'No (N)'	System	05 Aug 2020 17:00:21

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-05T10:00:14', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'd2e42245-0125-44ef-8cb9-5e1f55335fe7'	System	05 Aug 2020 17:00:21
User entered 'None (1)'	System	05 Aug 2020 17:00:21



US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-05T10:00:17', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'd2e42245-0125-44ef-8cb9-5e1f55335fe7'	System	05 Aug 2020 17:00:21
User entered '05 Aug 2020 10:00'	System	05 Aug 2020 17:00:21

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '05 Aug 2020 09:42'	System	05 Aug 2020 16:41:51

**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '05 Aug 2020 12:12'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	05 Aug 2020 16:41:51
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-05T21:01:21', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'c4c7ff85-9ff1-4826-a2cc-b740f5a5decf'	System	06 Aug 2020 04:01:55
User entered 'None (1)'	System	06 Aug 2020 04:01:55

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-05T21:01:26', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'c4c7ff85-9ff1-4826-a2cc-b740f5a5decf'	System	06 Aug 2020 04:01:55
User entered 'No (N)'	System	06 Aug 2020 04:01:55

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-05T21:01:33', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'c4c7ff85-9ff1-4826-a2cc-b740f5a5decf'	System	06 Aug 2020 04:01:55
User entered 'No (N)'	System	06 Aug 2020 04:01:55

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-05T21:01:47', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'c4c7ff85-9ff1-4826-a2cc-b740f5a5decf'	System	06 Aug 2020 04:01:55
User entered 'None (1)'	System	06 Aug 2020 04:01:55



US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-05T21:01:50', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'c4c7ff85-9ff1-4826-a2cc-b740f5a5decf'	System	06 Aug 2020 04:01:55
User entered '05 Aug 2020 21:01'	System	06 Aug 2020 04:01:55

**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '05 Aug 2020 13:07'	System	05 Aug 2020 16:41:51

**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	05 Aug 2020 16:41:51
User entered 'Day 2'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-06T13:59:54', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '254128e2-bca4-413d-97ea-fb70d68a9088'	System	06 Aug 2020 21:00:19
User entered 'None (1)'	System	06 Aug 2020 21:00:19

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:46:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-06T13:59:59', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '254128e2-bca4-413d-97ea-fb70d68a9088'	System	06 Aug 2020 21:00:19
User entered 'No (N)'	System	06 Aug 2020 21:00:19

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-06T14:00:01', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '254128e2-bca4-413d-97ea-fb70d68a9088'	System	06 Aug 2020 21:00:19
User entered 'No (N)'	System	06 Aug 2020 21:00:19

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-06T14:00:09', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '254128e2-bca4-413d-97ea-fb70d68a9088'	System	06 Aug 2020 21:00:19
User entered 'None (1)'	System	06 Aug 2020 21:00:19



US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:46:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-06T14:00:13', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '254128e2-bca4-413d-97ea-fb70d68a9088'	System	06 Aug 2020 21:00:19
User entered '06 Aug 2020 14:00'	System	06 Aug 2020 21:00:19

**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 16:41:51

**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	05 Aug 2020 16:41:51
User entered 'Day 3'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-07T15:39:28', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'ed75dee3-ed8f-4322-b1c3-7757a558e7c3'	System	07 Aug 2020 22:39:54
User entered 'Does not interfere with activity (2)'	System	07 Aug 2020 22:39:54

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:46:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-07T15:39:37', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'ed75dee3-ed8f-4322-b1c3-7757a558e7c3'	System	07 Aug 2020 22:39:54
User entered 'No (N)'	System	07 Aug 2020 22:39:54

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-07T15:39:39', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'ed75dee3-ed8f-4322-b1c3-7757a558e7c3'	System	07 Aug 2020 22:39:54
User entered 'No (N)'	System	07 Aug 2020 22:39:54

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-07T15:39:46', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'ed75dee3-ed8f-4322-b1c3-7757a558e7c3'	System	07 Aug 2020 22:39:54
User entered 'None (1)'	System	07 Aug 2020 22:39:54



US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:46:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-07T15:39:50', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'ed75dee3-ed8f-4322-b1c3-7757a558e7c3'	System	07 Aug 2020 22:39:54
User entered '07 Aug 2020 15:39'	System	07 Aug 2020 22:39:54

**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 16:41:51

**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	05 Aug 2020 16:41:51
User entered 'Day 4'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-08T12:10:42', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'f01a006f-c7f1-4a56-b0f5-e5b6e741bdf8'	System	09 Aug 2020 00:07:46
User entered 'None (1)'	System	09 Aug 2020 00:07:46

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:46:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-08T12:10:45', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'f01a006f-c7f1-4a56-b0f5-e5b6e741bdf8'	System	09 Aug 2020 00:07:46
User entered 'No (N)'	System	09 Aug 2020 00:07:46

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-08T12:10:48', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'f01a006f-c7f1-4a56-b0f5-e5b6e741bdf8'	System	09 Aug 2020 00:07:46
User entered 'No (N)'	System	09 Aug 2020 00:07:46

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-08T12:10:52', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'f01a006f-c7f1-4a56-b0f5-e5b6e741bdf8'	System	09 Aug 2020 00:07:46
User entered 'None (1)'	System	09 Aug 2020 00:07:46



US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:46:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-08T12:10:54', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'f01a006f-c7f1-4a56-b0f5-e5b6e741bdf8'	System	09 Aug 2020 00:07:46
User entered '08 Aug 2020 12:10'	System	09 Aug 2020 00:07:46

**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 16:41:51

**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	05 Aug 2020 16:41:51
User entered 'Day 5'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-09T17:14:40', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '3c3aa947-f1f6-40c4-91da-417da52da00a'	System	10 Aug 2020 00:14:54
User entered 'None (1)'	System	10 Aug 2020 00:14:54

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-09T17:14:42', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '3c3aa947-f1f6-40c4-91da-417da52da00a'	System	10 Aug 2020 00:14:54
User entered 'No (N)'	System	10 Aug 2020 00:14:54

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-09T17:14:46', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '3c3aa947-f1f6-40c4-91da-417da52da00a'	System	10 Aug 2020 00:14:54
User entered 'No (N)'	System	10 Aug 2020 00:14:54

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-09T17:14:49', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '3c3aa947-f1f6-40c4-91da-417da52da00a'	System	10 Aug 2020 00:14:54
User entered 'None (1)'	System	10 Aug 2020 00:14:54



US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:46:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-09T17:14:52', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '3c3aa947-f1f6-40c4-91da-417da52da00a'	System	10 Aug 2020 00:14:54
User entered '09 Aug 2020 17:14'	System	10 Aug 2020 00:14:54

**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 16:41:51

**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	05 Aug 2020 16:41:51
User entered 'Day 6'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-11T09:07:58', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '0542ab90-abb6-4671-a5c7-94fc10df4728'	System	11 Aug 2020 16:08:13
User entered 'None (1)'	System	11 Aug 2020 16:08:13

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:46:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-11T09:08:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '0542ab90-abb6-4671-a5c7-94fc10df4728'	System	11 Aug 2020 16:08:13
User entered 'No (N)'	System	11 Aug 2020 16:08:13

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-11T09:08:06', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '0542ab90-abb6-4671-a5c7-94fc10df4728'	System	11 Aug 2020 16:08:13
User entered 'No (N)'	System	11 Aug 2020 16:08:13

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-11T09:08:08', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '0542ab90-abb6-4671-a5c7-94fc10df4728'	System	11 Aug 2020 16:08:13
User entered 'None (1)'	System	11 Aug 2020 16:08:13



US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:46:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-11T09:08:10', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '0542ab90-abb6-4671-a5c7-94fc10df4728'	System	11 Aug 2020 16:08:13
User entered '11 Aug 2020 09:08'	System	11 Aug 2020 16:08:13

**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 16:41:51

**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	05 Aug 2020 16:41:51
User entered 'Day 7'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-12T08:44:29', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'cb0086be-6cf0-483f-9990-2ed6a4e4dae6'	System	12 Aug 2020 15:44:45
User entered 'None (1)'	System	12 Aug 2020 15:44:45

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:46:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-12T08:44:31', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'cb0086be-6cf0-483f-9990-2ed6a4e4dae6'	System	12 Aug 2020 15:44:45
User entered 'No (N)'	System	12 Aug 2020 15:44:45

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-12T08:44:33', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'cb0086be-6cf0-483f-9990-2ed6a4e4dae6'	System	12 Aug 2020 15:44:45
User entered 'No (N)'	System	12 Aug 2020 15:44:45

US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-12T08:44:36', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'cb0086be-6cf0-483f-9990-2ed6a4e4dae6'	System	12 Aug 2020 15:44:45
User entered 'None (1)'	System	12 Aug 2020 15:44:45



US3772007

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:46:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-12T08:44:42', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'cb0086be-6cf0-483f-9990-2ed6a4e4dae6'	System	12 Aug 2020 15:44:45
User entered '12 Aug 2020 08:44'	System	12 Aug 2020 15:44:45

**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 16:41:51

**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	05 Aug 2020 16:41:51
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-05T10:00:23', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '00828f8d-68cf-470b-9df1-8946a0617158'	System	05 Aug 2020 17:00:45
User entered 'None (0)'	System	05 Aug 2020 17:00:45

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-05T10:00:25', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '00828f8d-68cf-470b-9df1-8946a0617158'	System	05 Aug 2020 17:00:45
User entered 'None (0)'	System	05 Aug 2020 17:00:45

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-05T10:00:27', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '00828f8d-68cf-470b-9df1-8946a0617158'	System	05 Aug 2020 17:00:45
User entered 'None (0)'	System	05 Aug 2020 17:00:45

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-05T10:00:29', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '00828f8d-68cf-470b-9df1-8946a0617158'	System	05 Aug 2020 17:00:45
User entered 'None (0)'	System	05 Aug 2020 17:00:45



US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-05T10:00:32', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '00828f8d-68cf-470b-9df1-8946a0617158'	System	05 Aug 2020 17:00:45
User entered 'None (0)'	System	05 Aug 2020 17:00:45

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-05T10:00:34', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '00828f8d-68cf-470b-9df1-8946a0617158'	System	05 Aug 2020 17:00:45
User entered 'None (0)'	System	05 Aug 2020 17:00:45

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-05T10:00:37', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '00828f8d-68cf-470b-9df1-8946a0617158'	System	05 Aug 2020 17:00:45
User entered 'No (N)'	System	05 Aug 2020 17:00:45

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-05T10:00:42', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '00828f8d-68cf-470b-9df1-8946a0617158'	System	05 Aug 2020 17:00:45
User entered '05 Aug 2020 10:00'	System	05 Aug 2020 17:00:45

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '05 Aug 2020 09:42'	System	05 Aug 2020 16:41:51

**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '05 Aug 2020 12:12'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	05 Aug 2020 16:41:51
User entered 'Day 1, after vaccination (at home)'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-05T21:01:55', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'cee2c214-907c-4ccf-90c7-d2b266d638ca'	System	06 Aug 2020 04:02:27
User entered 'No interference with activity (1)'	System	06 Aug 2020 04:02:27



US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-05T21:01:59', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'cee2c214-907c-4ccf-90c7-d2b266d638ca'	System	06 Aug 2020 04:02:27
User entered 'No interference with activity (1)'	System	06 Aug 2020 04:02:27

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-05T21:02:03', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'cee2c214-907c-4ccf-90c7-d2b266d638ca'	System	06 Aug 2020 04:02:27
User entered 'None (0)'	System	06 Aug 2020 04:02:27

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-05T21:02:06', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'cee2c214-907c-4ccf-90c7-d2b266d638ca'	System	06 Aug 2020 04:02:27
User entered 'None (0)'	System	06 Aug 2020 04:02:27

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-05T21:02:09', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'cee2c214-907c-4ccf-90c7-d2b266d638ca'	System	06 Aug 2020 04:02:27
User entered 'None (0)'	System	06 Aug 2020 04:02:27

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-05T21:02:12', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'cee2c214-907c-4ccf-90c7-d2b266d638ca'	System	06 Aug 2020 04:02:27
User entered 'None (0)'	System	06 Aug 2020 04:02:27

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-05T21:02:20', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'cee2c214-907c-4ccf-90c7-d2b266d638ca'	System	06 Aug 2020 04:02:27
User entered 'No (N)'	System	06 Aug 2020 04:02:27

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-05T21:02:23', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'cee2c214-907c-4ccf-90c7-d2b266d638ca'	System	06 Aug 2020 04:02:27
User entered '05 Aug 2020 21:02'	System	06 Aug 2020 04:02:27

**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '05 Aug 2020 13:07'	System	05 Aug 2020 16:41:51



**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '06 Aug 2020 11:59'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	05 Aug 2020 16:41:51
User entered 'Day 2'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:46:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-06T14:00:18', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'd82987f2-edel-447b-9c63-642446e74c7c'	System	06 Aug 2020 21:00:37
User entered 'None (0)'	System	06 Aug 2020 21:00:37

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:46:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-06T14:00:21', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'd82987f2-edel-447b-9c63-642446e74c7c'	System	06 Aug 2020 21:00:37
User entered 'None (0)'	System	06 Aug 2020 21:00:37

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:46:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-06T14:00:23', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'd82987f2-edel-447b-9c63-642446e74c7c'	System	06 Aug 2020 21:00:37
User entered 'None (0)'	System	06 Aug 2020 21:00:37

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:46:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-06T14:00:25', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'd82987f2-edel-447b-9c63-642446e74c7c'	System	06 Aug 2020 21:00:37
User entered 'None (0)'	System	06 Aug 2020 21:00:37

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:46:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-06T14:00:27', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'd82987f2-edel-447b-9c63-642446e74c7c'	System	06 Aug 2020 21:00:37
User entered 'None (0)'	System	06 Aug 2020 21:00:37

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:46:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-06T14:00:29', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'd82987f2-edel-447b-9c63-642446e74c7c'	System	06 Aug 2020 21:00:37
User entered 'None (0)'	System	06 Aug 2020 21:00:37



US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-06T14:00:32', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'd82987f2-edel-447b-9c63-642446e74c7c'	System	06 Aug 2020 21:00:37
User entered 'No (N)'	System	06 Aug 2020 21:00:37

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:46:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-06T14:00:34', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'd82987f2-edel-447b-9c63-642446e74c7c'	System	06 Aug 2020 21:00:37
User entered '06 Aug 2020 14:00'	System	06 Aug 2020 21:00:37

**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '06 Aug 2020 12:00'	System	05 Aug 2020 16:41:51

**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '07 Aug 2020 11:59'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	05 Aug 2020 16:41:51
User entered 'Day 3'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:46:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-07T15:39:55', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'cd91b43f-dd41-4feb-9dce-0258731f7270'	System	07 Aug 2020 22:40:18
User entered 'None (0)'	System	07 Aug 2020 22:40:18

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:46:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-07T15:39:57', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'cd91b43f-dd41-4feb-9dce-0258731f7270'	System	07 Aug 2020 22:40:18
User entered 'None (0)'	System	07 Aug 2020 22:40:18

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:46:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-07T15:40:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'cd91b43f-dd41-4feb-9dce-0258731f7270'	System	07 Aug 2020 22:40:18
User entered 'None (0)'	System	07 Aug 2020 22:40:18



US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:46:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-07T15:40:02', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'cd91b43f-dd41-4feb-9dce-0258731f7270'	System	07 Aug 2020 22:40:18
User entered 'None (0)'	System	07 Aug 2020 22:40:18

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:46:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-07T15:40:04', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'cd91b43f-dd41-4feb-9dce-0258731f7270'	System	07 Aug 2020 22:40:18
User entered 'None (0)'	System	07 Aug 2020 22:40:18

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:46:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-07T15:40:06', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'cd91b43f-dd41-4feb-9dce-0258731f7270'	System	07 Aug 2020 22:40:18
User entered 'None (0)'	System	07 Aug 2020 22:40:18

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-07T15:40:08', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'cd91b43f-dd41-4feb-9dce-0258731f7270'	System	07 Aug 2020 22:40:18
User entered 'No (N)'	System	07 Aug 2020 22:40:18

**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-07T15:40:12', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'cd91b43f-dd41-4feb-9dce-0258731f7270'	System	07 Aug 2020 22:40:18
User entered '07 Aug 2020 15:40'	System	07 Aug 2020 22:40:18

**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '07 Aug 2020 12:00'	System	05 Aug 2020 16:41:51

**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '08 Aug 2020 11:59'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	05 Aug 2020 16:41:51
User entered 'Day 4'	System	05 Aug 2020 16:41:51



US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:46:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-08T12:11:09', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '58e8e3c7-f292-4d78-8caf-79403b13e0e3'	System	09 Aug 2020 00:07:46
User entered 'None (0)'	System	09 Aug 2020 00:07:46

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:46:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-08T12:11:11', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '58e8e3c7-f292-4d78-8caf-79403b13e0e3'	System	09 Aug 2020 00:07:46
User entered 'None (0)'	System	09 Aug 2020 00:07:46

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:46:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-08T12:11:26', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '58e8e3c7-f292-4d78-8caf-79403b13e0e3'	System	09 Aug 2020 00:07:46
User entered 'None (0)'	System	09 Aug 2020 00:07:46

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:46:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-08T12:11:33', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '58e8e3c7-f292-4d78-8caf-79403b13e0e3'	System	09 Aug 2020 00:07:46
User entered 'None (0)'	System	09 Aug 2020 00:07:46

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:46:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-08T12:11:34', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '58e8e3c7-f292-4d78-8caf-79403b13e0e3'	System	09 Aug 2020 00:07:46
User entered 'None (0)'	System	09 Aug 2020 00:07:46

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:46:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-08T12:11:36', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '58e8e3c7-f292-4d78-8caf-79403b13e0e3'	System	09 Aug 2020 00:07:46
User entered 'None (0)'	System	09 Aug 2020 00:07:46

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-08T12:11:40', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '58e8e3c7-f292-4d78-8caf-79403b13e0e3'	System	09 Aug 2020 00:07:46
User entered 'No (N)'	System	09 Aug 2020 00:07:46

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:46:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-08T12:11:43', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '58e8e3c7-f292-4d78-8caf-79403b13e0e3'	System	09 Aug 2020 00:07:46
User entered '08 Aug 2020 12:11'	System	09 Aug 2020 00:07:46



**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '08 Aug 2020 12:00'	System	05 Aug 2020 16:41:51

**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '09 Aug 2020 11:59'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	05 Aug 2020 16:41:51
User entered 'Day 5'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:46:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-09T17:14:55', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'd711f9a9-99c3-40a7-8203-922a4a703350'	System	10 Aug 2020 00:15:17
User entered 'None (0)'	System	10 Aug 2020 00:15:17

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:46:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-09T17:14:57', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'd711f9a9-99c3-40a7-8203-922a4a703350'	System	10 Aug 2020 00:15:17
User entered 'None (0)'	System	10 Aug 2020 00:15:17

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:46:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-09T17:15:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'd711f9a9-99c3-40a7-8203-922a4a703350'	System	10 Aug 2020 00:15:17
User entered 'None (0)'	System	10 Aug 2020 00:15:17

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:46:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-09T17:15:05', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'd711f9a9-99c3-40a7-8203-922a4a703350'	System	10 Aug 2020 00:15:17
User entered 'None (0)'	System	10 Aug 2020 00:15:17

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:46:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-09T17:15:07', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'd711f9a9-99c3-40a7-8203-922a4a703350'	System	10 Aug 2020 00:15:17
User entered 'None (0)'	System	10 Aug 2020 00:15:17



US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:46:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-09T17:15:09', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'd711f9a9-99c3-40a7-8203-922a4a703350'	System	10 Aug 2020 00:15:17
User entered 'None (0)'	System	10 Aug 2020 00:15:17

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-09T17:15:12', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'd711f9a9-99c3-40a7-8203-922a4a703350'	System	10 Aug 2020 00:15:17
User entered 'No (N)'	System	10 Aug 2020 00:15:17

**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-09T17:15:15', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'd711f9a9-99c3-40a7-8203-922a4a703350'	System	10 Aug 2020 00:15:17
User entered '09 Aug 2020 17:15'	System	10 Aug 2020 00:15:17

**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '09 Aug 2020 12:00'	System	05 Aug 2020 16:41:51

**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '10 Aug 2020 11:59'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	05 Aug 2020 16:41:51
User entered 'Day 6'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:46:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-11T09:08:13', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'a5955dd7-0dc9-4e52-a690-66f7f9a2d730'	System	11 Aug 2020 16:08:26
User entered 'None (0)'	System	11 Aug 2020 16:08:26

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:46:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-11T09:08:14', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'a5955dd7-0dc9-4e52-a690-66f7f9a2d730'	System	11 Aug 2020 16:08:26
User entered 'None (0)'	System	11 Aug 2020 16:08:26



US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:46:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-11T09:08:15', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'a5955dd7-0dc9-4e52-a690-66f7f9a2d730'	System	11 Aug 2020 16:08:26
User entered 'None (0)'	System	11 Aug 2020 16:08:26

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:46:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-11T09:08:17', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'a5955dd7-0dc9-4e52-a690-66f7f9a2d730'	System	11 Aug 2020 16:08:26
User entered 'None (0)'	System	11 Aug 2020 16:08:26

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:46:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-11T09:08:18', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'a5955dd7-0dc9-4e52-a690-66f7f9a2d730'	System	11 Aug 2020 16:08:26
User entered 'None (0)'	System	11 Aug 2020 16:08:26

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:46:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-11T09:08:20', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'a5955dd7-0dc9-4e52-a690-66f7f9a2d730'	System	11 Aug 2020 16:08:26
User entered 'None (0)'	System	11 Aug 2020 16:08:26

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-11T09:08:22', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'a5955dd7-0dc9-4e52-a690-66f7f9a2d730'	System	11 Aug 2020 16:08:26
User entered 'No (N)'	System	11 Aug 2020 16:08:26

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:46:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-11T09:08:24', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'a5955dd7-0dc9-4e52-a690-66f7f9a2d730'	System	11 Aug 2020 16:08:26
User entered '11 Aug 2020 09:08'	System	11 Aug 2020 16:08:26

**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '10 Aug 2020 12:00'	System	05 Aug 2020 16:41:51

**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '11 Aug 2020 11:59'	System	05 Aug 2020 16:41:51



US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	05 Aug 2020 16:41:51
User entered 'Day 7'	System	05 Aug 2020 16:41:51

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:46:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-12T08:44:45', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '5c1f95ad-cd2e-41f8-87ca-0f4d1d014956'	System	12 Aug 2020 15:45:09
User entered 'None (0)'	System	12 Aug 2020 15:45:09

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:46:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-12T08:44:46', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '5c1f95ad-cd2e-41f8-87ca-0f4d1d014956'	System	12 Aug 2020 15:45:09
User entered 'None (0)'	System	12 Aug 2020 15:45:09

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:46:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-12T08:44:48', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '5c1f95ad-cd2e-41f8-87ca-0f4d1d014956'	System	12 Aug 2020 15:45:09
User entered 'None (0)'	System	12 Aug 2020 15:45:09

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:46:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-12T08:44:49', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '5c1f95ad-cd2e-41f8-87ca-0f4d1d014956'	System	12 Aug 2020 15:45:09
User entered 'None (0)'	System	12 Aug 2020 15:45:09

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:46:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-12T08:44:51', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '5c1f95ad-cd2e-41f8-87ca-0f4d1d014956'	System	12 Aug 2020 15:45:09
User entered 'None (0)'	System	12 Aug 2020 15:45:09

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:46:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-12T08:44:52', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '5c1f95ad-cd2e-41f8-87ca-0f4d1d014956'	System	12 Aug 2020 15:45:09
User entered 'None (0)'	System	12 Aug 2020 15:45:09

US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-12T08:44:55', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '5c1f95ad-cd2e-41f8-87ca-0f4d1d014956'	System	12 Aug 2020 15:45:09
User entered 'No (N)'	System	12 Aug 2020 15:45:09



US3772007

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:46:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-08-12T08:45:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '5c1f95ad-cd2e-41f8-87ca-0f4d1d014956'	System	12 Aug 2020 15:45:09
User entered '12 Aug 2020 08:45'	System	12 Aug 2020 15:45:09

**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '11 Aug 2020 12:00'	System	05 Aug 2020 16:41:51

**US3772007**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '12 Aug 2020 11:59'	System	05 Aug 2020 16:41:51

**US3772007**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:46:07**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 22:40:18

US3772007

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '12 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 22:40:18

**US3772007**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:46:07**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	19 Aug 2020 22:40:18

US3772007

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:07

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 22:40:18

US3772007

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 22:40:25



**US3772007**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:46:07**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered 'I'	System	19 Aug 2020 22:40:25

**US3772007**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:46:07**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 22:50:44

**US3772007**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:46:07**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 22:50:44

US3772007

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 22:50:44

US3772007

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:07

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 22:50:44

US3772007

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 22:50:51

**US3772007**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:46:07**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered 'I'	System	19 Aug 2020 22:50:51

US3772007

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 21:39:06



**US3772007**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:46:07**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 21:39:06

US3772007

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 21:39:06

US3772007

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:07

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 21:39:06

US3772007

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 21:39:13

**US3772007**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:46:07**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered 'I'	System	26 Aug 2020 21:39:13

US3772007

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:46:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:19:24

US3772007

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '08 Sep 2020'	(b) (4) Emily Crews (b) (4)	09 Sep 2020 00:19:24

US3772007

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Clinic (Clinic)'	Emily Crews (b) (4)	09 Sep 2020 00:19:24



**US3772007**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:46:07**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered 'VISIT2'	System	09 Sep 2020 00:19:24

US3772007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User accepted default value 'Pre-Dose (PREDOSE)'	Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:51:13

US3772007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:51:13

US3772007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '08 Sep 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:51:13

US3772007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '15:45'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:51:13

US3772007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered '08 Sep 2020 15:45'	System	09 Sep 2020 00:51:13

US3772007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '37.2' C	(b) (4) Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:51:13

US3772007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Oral (Oral)'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:51:13



US3772007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:51:13

US3772007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '91'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:51:13

US3772007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered 'bpm'	System	09 Sep 2020 00:51:13

US3772007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '16'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:51:13

US3772007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered 'breaths/min'	System	09 Sep 2020 00:51:13

US3772007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '133'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:51:13

US3772007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered 'mmHg'	System	09 Sep 2020 00:51:13

US3772007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '87'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:51:13



US3772007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:46:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered 'mmHg'	System	09 Sep 2020 00:51:13

US3772007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:07

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User accepted default value 'Post-Dose (POSTDOSE)'	Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:51:13

US3772007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:51:13

US3772007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '08 Sep 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:51:13

**US3772007**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:46:07**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '17:30'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:51:13

US3772007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered '08 Sep 2020 17:30'	System	09 Sep 2020 00:51:13

US3772007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '37.2' C	(b) (4) Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:51:13

US3772007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Oral (Oral)'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:51:13



US3772007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:51:13

US3772007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '55'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:51:13

US3772007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered 'bpm'	System	09 Sep 2020 00:51:13

US3772007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '14'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:51:13

US3772007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered 'breaths/min'	System	09 Sep 2020 00:51:13

US3772007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '125'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:51:13

US3772007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered 'mmHg'	System	09 Sep 2020 00:51:13

US3772007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '78'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:51:13



US3772007

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:46:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered 'mmHg'	System	09 Sep 2020 00:51:13

US3772007

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:46:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:19:31

US3772007

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:46:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '08 Sep 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:19:31

US3772007

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:46:07

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:19:47

US3772007

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:46:07

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:19:47

US3772007

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:19:47

US3772007

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:46:07

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered 'MRNA-1273 OR PLACEBO'	System	09 Sep 2020 00:19:47

US3772007

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:46:07

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '08 Sep 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:19:47



US3772007

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:46:07

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '16:54'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:19:47

US3772007

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:46:07

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered '08 Sep 2020 16:54'	System	09 Sep 2020 00:19:47

US3772007

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:46:07

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Left Arm (LEFT ARM)'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:19:47

US3772007

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:46:07

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered 'ONCE'	System	09 Sep 2020 00:19:47

US3772007

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:46:07

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered 'INTRAMUSCULAR'	System	09 Sep 2020 00:19:47

US3772007

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:46:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:19:59

US3772007

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:46:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '08 Sep 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:19:59

US3772007

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:46:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '16:00'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:19:59



US3772007

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:46:07

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered '08 Sep 2020 16:00'	System	09 Sep 2020 00:19:59

US3772007

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:46:07

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '08 Sep 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:20:12

US3772007

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:46:07

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:20:12

US3772007

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:46:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:20:12

US3772007

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:46:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '16:05'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:20:12

**US3772007**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:46:07**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered '08 Sep 2020 16:05'	System	09 Sep 2020 00:20:12

US3772007

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:46:07

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:20:12

US3772007

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:46:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:20:12



US3772007

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:46:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:20:12

**US3772007**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:46:07**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered empty.	System	09 Sep 2020 00:20:12

US3772007

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	09 Sep 2020 00:20:16

US3772007

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered '1'	System	09 Sep 2020 00:20:16

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	09 Sep 2020 00:19:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-08T17:28:29', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '880977cf-d797-42ab-afe6-f6b6a9044deb'	System	09 Sep 2020 00:28:41
User entered 'Yes (Y)'	System	09 Sep 2020 00:28:41

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-08T17:28:32', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '880977cf-d797-42ab-afe6-f6b6a9044deb'	System	09 Sep 2020 00:28:41
User entered '98.9'	System	09 Sep 2020 00:28:41

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-08T17:28:35', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '880977cf-d797-42ab-afe6-f6b6a9044deb'	System	09 Sep 2020 00:28:41
User entered 'No (N)'	System	09 Sep 2020 00:28:41



US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-08T17:28:38', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '880977cf-d797-42ab-afe6-f6b6a9044deb'	System	09 Sep 2020 00:28:41
User entered '08 Sep 2020 17:28'	System	09 Sep 2020 00:28:41

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '08 Sep 2020 17:14'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '08 Sep 2020 19:44'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	09 Sep 2020 00:19:47
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-09T08:40:42', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '38df22c8-c0d2-4759-8c5e-e19adf425636'	System	09 Sep 2020 15:40:59
User entered 'Yes (Y)'	System	09 Sep 2020 15:40:59

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-09T08:40:47', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '38df22c8-c0d2-4759-8c5e-e19adf425636'	System	09 Sep 2020 15:40:59
User entered '98.8'	System	09 Sep 2020 15:40:59

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-09T08:40:50', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '38df22c8-c0d2-4759-8c5e-e19adf425636'	System	09 Sep 2020 15:40:59
User entered 'No (N)'	System	09 Sep 2020 15:40:59

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-09T08:40:55', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '38df22c8-c0d2-4759-8c5e-e19adf425636'	System	09 Sep 2020 15:40:59
User entered '09 Sep 2020 08:40'	System	09 Sep 2020 15:40:59



US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '08 Sep 2020 20:39'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '09 Sep 2020 11:59'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	09 Sep 2020 00:19:47
User entered 'Day 2'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:46:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-09T22:37:48', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '9f5a981e-b172-46d4-862f-3405db92bdde'	System	10 Sep 2020 05:38:02
User entered 'Yes (Y)'	System	10 Sep 2020 05:38:02

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:46:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-09T22:37:52', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '9f5a981e-b172-46d4-862f-3405db92bdde'	System	10 Sep 2020 05:38:02
User entered '98.5'	System	10 Sep 2020 05:38:02

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-09T22:37:56', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '9f5a981e-b172-46d4-862f-3405db92bdde'	System	10 Sep 2020 05:38:02
User entered 'No (N)'	System	10 Sep 2020 05:38:02

**US3772007**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-09T22:37:59', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '9f5a981e-b172-46d4-862f-3405db92bdde'	System	10 Sep 2020 05:38:02
User entered '09 Sep 2020 22:37'	System	10 Sep 2020 05:38:02

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:46:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '09 Sep 2020 12:00'	System	09 Sep 2020 00:19:47



US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:46:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	09 Sep 2020 00:19:47
User entered 'Day 3'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:46:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-10T15:52:37', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'ae854605-bd81-40fa-9224-13afdcbc3399'	System	10 Sep 2020 22:52:52
User entered 'Yes (Y)'	System	10 Sep 2020 22:52:52

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:46:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-10T15:52:41', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'ae854605-bd81-40fa-9224-13afdcbc3399'	System	10 Sep 2020 22:52:52
User entered '98.1'	System	10 Sep 2020 22:52:52

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-10T15:52:44', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'ae854605-bd81-40fa-9224-13afdcabc3399'	System	10 Sep 2020 22:52:52
User entered 'No (N)'	System	10 Sep 2020 22:52:52

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:46:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-10T15:52:47', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'ae854605-bd81-40fa-9224-13afdcbc3399'	System	10 Sep 2020 22:52:52
User entered '10 Sep 2020 15:52'	System	10 Sep 2020 22:52:52

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:46:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:46:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 00:19:47



US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	09 Sep 2020 00:19:47
User entered 'Day 4'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:46:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:46:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:46:07

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:46:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:46:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 00:19:47



US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:46:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	09 Sep 2020 00:19:47
User entered 'Day 5'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:46:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-12T23:51:45', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '6f98d481-3195-43dd-a660-537a0397aa02'	System	13 Sep 2020 06:51:59
User entered 'Yes (Y)'	System	13 Sep 2020 06:51:59

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:46:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-12T23:51:49', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '6f98d481-3195-43dd-a660-537a0397aa02'	System	13 Sep 2020 06:51:59
User entered '99.1'	System	13 Sep 2020 06:51:59

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-12T23:51:52', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '6f98d481-3195-43dd-a660-537a0397aa02'	System	13 Sep 2020 06:51:59
User entered 'No (N)'	System	13 Sep 2020 06:51:59

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:46:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-12T23:51:56', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '6f98d481-3195-43dd-a660-537a0397aa02'	System	13 Sep 2020 06:51:59
User entered '12 Sep 2020 23:51'	System	13 Sep 2020 06:51:59

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:46:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 00:19:47

**US3772007**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 00:19:47



US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	09 Sep 2020 00:19:47
User entered 'Day 6'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:46:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-14T08:30:30', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '9b34e99d-a9f9-4907-b4a6-739c3412c336'	System	14 Sep 2020 15:30:44
User entered 'Yes (Y)'	System	14 Sep 2020 15:30:44

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:46:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-14T08:30:34', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '9b34e99d-a9f9-4907-b4a6-739c3412c336'	System	14 Sep 2020 15:30:44
User entered '98.7'	System	14 Sep 2020 15:30:44

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-14T08:30:37', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '9b34e99d-a9f9-4907-b4a6-739c3412c336'	System	14 Sep 2020 15:30:44
User entered 'No (N)'	System	14 Sep 2020 15:30:44

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:46:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-14T08:30:40', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '9b34e99d-a9f9-4907-b4a6-739c3412c336'	System	14 Sep 2020 15:30:44
User entered '14 Sep 2020 08:30'	System	14 Sep 2020 15:30:44

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:46:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 00:19:47

**US3772007**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	09 Sep 2020 00:19:47
User entered 'Day 7'	System	09 Sep 2020 00:19:47



US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:46:07

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-15T08:11:35', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '912ad9ac-1639-4dfb-a842-baf5d6777be0'	System	15 Sep 2020 15:11:57
User entered 'Yes (Y)'	System	15 Sep 2020 15:11:57

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:46:07

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-15T08:11:41', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '912ad9ac-1639-4dfb-a842-baf5d6777be0'	System	15 Sep 2020 15:11:57
User entered '98.6'	System	15 Sep 2020 15:11:57

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-15T08:11:44', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '912ad9ac-1639-4dfb-a842-baf5d6777be0'	System	15 Sep 2020 15:11:57
User entered 'No (N)'	System	15 Sep 2020 15:11:57

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:46:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-15T08:11:54', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '912ad9ac-1639-4dfb-a842-baf5d6777be0'	System	15 Sep 2020 15:11:57
User entered '15 Sep 2020 08:11'	System	15 Sep 2020 15:11:57

US3772007

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:46:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 00:19:47

**US3772007**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	09 Sep 2020 00:19:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-08T17:28:41', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'cc571f00-a388-43a3-80d5-070d664be826'	System	09 Sep 2020 00:28:56
User entered 'None (1)'	System	09 Sep 2020 00:28:56



US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-08T17:28:44', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'cc571f00-a388-43a3-80d5-070d664be826'	System	09 Sep 2020 00:28:56
User entered 'No (N)'	System	09 Sep 2020 00:28:56

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-08T17:28:46', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'cc571f00-a388-43a3-80d5-070d664be826'	System	09 Sep 2020 00:28:56
User entered 'No (N)'	System	09 Sep 2020 00:28:56

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-08T17:28:50', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'cc571f00-a388-43a3-80d5-070d664be826'	System	09 Sep 2020 00:28:56
User entered 'None (1)'	System	09 Sep 2020 00:28:56

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-08T17:28:52', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'cc571f00-a388-43a3-80d5-070d664be826'	System	09 Sep 2020 00:28:56
User entered '08 Sep 2020 17:28'	System	09 Sep 2020 00:28:56

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '08 Sep 2020 17:14'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '08 Sep 2020 19:44'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	09 Sep 2020 00:19:47
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-09T08:40:59', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '3812838e-79b4-45c0-af38-b23c716d1a8a'	System	09 Sep 2020 15:41:14
User entered 'None (1)'	System	09 Sep 2020 15:41:14



US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-09T08:41:03', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '3812838e-79b4-45c0-af38-b23c716d1a8a'	System	09 Sep 2020 15:41:14
User entered 'No (N)'	System	09 Sep 2020 15:41:14

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-09T08:41:06', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '3812838e-79b4-45c0-af38-b23c716d1a8a'	System	09 Sep 2020 15:41:14
User entered 'No (N)'	System	09 Sep 2020 15:41:14

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-09T08:41:09', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '3812838e-79b4-45c0-af38-b23c716d1a8a'	System	09 Sep 2020 15:41:14
User entered 'None (1)'	System	09 Sep 2020 15:41:14

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-09T08:41:11', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '3812838e-79b4-45c0-af38-b23c716d1a8a'	System	09 Sep 2020 15:41:14
User entered '09 Sep 2020 08:41'	System	09 Sep 2020 15:41:14

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '08 Sep 2020 20:39'	System	09 Sep 2020 00:19:47

**US3772007**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '09 Sep 2020 11:59'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	09 Sep 2020 00:19:47
User entered 'Day 2'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-09T22:38:03', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '68ff7866-704b-4f1d-aaf6-1780b7c0549f'	System	10 Sep 2020 05:38:14
User entered 'None (1)'	System	10 Sep 2020 05:38:14



US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-09T22:38:05', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '68ff7866-704b-4f1d-aaf6-1780b7c0549f'	System	10 Sep 2020 05:38:14
User entered 'No (N)'	System	10 Sep 2020 05:38:14

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-09T22:38:07', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '68ff7866-704b-4f1d-aaf6-1780b7c0549f'	System	10 Sep 2020 05:38:14
User entered 'No (N)'	System	10 Sep 2020 05:38:14

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-09T22:38:09', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '68ff7866-704b-4f1d-aaf6-1780b7c0549f'	System	10 Sep 2020 05:38:14
User entered 'None (1)'	System	10 Sep 2020 05:38:14

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:46:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-09T22:38:12', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '68ff7866-704b-4f1d-aaf6-1780b7c0549f' User entered '09 Sep 2020 22:38'	System	10 Sep 2020 05:38:14
	System	10 Sep 2020 05:38:14

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:46:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '09 Sep 2020 12:00'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:46:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	09 Sep 2020 00:19:47
User entered 'Day 3'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-10T15:52:50', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'a6337fa5-b3b4-4bcc-bcdc-c4d705b5070c'	System	10 Sep 2020 22:53:09
User entered 'None (1)'	System	10 Sep 2020 22:53:09



US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:46:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-10T15:52:54', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'a6337fa5-b3b4-4bcc-bcdc-c4d705b5070c'	System	10 Sep 2020 22:53:09
User entered 'No (N)'	System	10 Sep 2020 22:53:09

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-10T15:52:56', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'a6337fa5-b3b4-4bcc-bcdc-c4d705b5070c'	System	10 Sep 2020 22:53:09
User entered 'No (N)'	System	10 Sep 2020 22:53:09

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-10T15:52:58', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'a6337fa5-b3b4-4bcc-bcdc-c4d705b5070c'	System	10 Sep 2020 22:53:09
User entered 'None (1)'	System	10 Sep 2020 22:53:09

**US3772007**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-10T15:53:07', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'a6337fa5-b3b4-4bcc-bcdc-c4d705b5070c'	System	10 Sep 2020 22:53:09
User entered '10 Sep 2020 15:53'	System	10 Sep 2020 22:53:09

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:46:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:46:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	09 Sep 2020 00:19:47
User entered 'Day 4'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20



US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:46:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:46:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20

**US3772007**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:46:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 00:19:47



US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	09 Sep 2020 00:19:47
User entered 'Day 5'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-12T23:52:04', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '201ea8a2-4e44-40fc-8ca1-3075efd55ad1'	System	13 Sep 2020 06:52:20
User entered 'None (1)'	System	13 Sep 2020 06:52:20

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:46:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-12T23:52:06', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '201ea8a2-4e44-40fc-8ca1-3075efd55ad1'	System	13 Sep 2020 06:52:20
User entered 'No (N)'	System	13 Sep 2020 06:52:20

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-12T23:52:08', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '201ea8a2-4e44-40fc-8ca1-3075efd55ad1'	System	13 Sep 2020 06:52:20
User entered 'No (N)'	System	13 Sep 2020 06:52:20

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-12T23:52:15', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '201ea8a2-4e44-40fc-8ca1-3075efd55ad1'	System	13 Sep 2020 06:52:20
User entered 'None (1)'	System	13 Sep 2020 06:52:20

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:46:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-12T23:52:18', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '201ea8a2-4e44-40fc-8ca1-3075efd55ad1'	System	13 Sep 2020 06:52:20
User entered '12 Sep 2020 23:52'	System	13 Sep 2020 06:52:20

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:46:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:46:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 00:19:47



US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	09 Sep 2020 00:19:47
User entered 'Day 6'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-14T08:30:44', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '4c04cfac-c3cc-41e9-8296-4abc5336f387'	System	14 Sep 2020 15:30:58
User entered 'None (1)'	System	14 Sep 2020 15:30:58

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:46:07

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-14T08:30:46', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '4c04cfac-c3cc-41e9-8296-4abc5336f387'	System	14 Sep 2020 15:30:58
User entered 'No (N)'	System	14 Sep 2020 15:30:58

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-14T08:30:48', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '4c04cfac-c3cc-41e9-8296-4abc5336f387'	System	14 Sep 2020 15:30:58
User entered 'No (N)'	System	14 Sep 2020 15:30:58

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-14T08:30:51', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '4c04cfac-c3cc-41e9-8296-4abc5336f387'	System	14 Sep 2020 15:30:58
User entered 'None (1)'	System	14 Sep 2020 15:30:58

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:46:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-14T08:30:53', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '4c04cfac-c3cc-41e9-8296-4abc5336f387'	System	14 Sep 2020 15:30:58
User entered '14 Sep 2020 08:30'	System	14 Sep 2020 15:30:58

**US3772007**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:46:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 00:19:47



US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	09 Sep 2020 00:19:47
User entered 'Day 7'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-15T08:11:58', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '03ff02b4-8523-45da-903a-a6869005bc0d'	System	15 Sep 2020 15:12:19
User entered 'None (1)'	System	15 Sep 2020 15:12:19

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-15T08:12:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '03ff02b4-8523-45da-903a-a6869005bc0d'	System	15 Sep 2020 15:12:19
User entered 'No (N)'	System	15 Sep 2020 15:12:19

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-15T08:12:03', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '03ff02b4-8523-45da-903a-a6869005bc0d'	System	15 Sep 2020 15:12:19
User entered 'No (N)'	System	15 Sep 2020 15:12:19

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-15T08:12:07', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '03ff02b4-8523-45da-903a-a6869005bc0d'	System	15 Sep 2020 15:12:19
User entered 'None (1)'	System	15 Sep 2020 15:12:19

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:46:07

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-15T08:12:15', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '03ff02b4-8523-45da-903a-a6869005bc0d'	System	15 Sep 2020 15:12:19
User entered '15 Sep 2020 08:12'	System	15 Sep 2020 15:12:19

**US3772007**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:46:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 00:19:47



US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	09 Sep 2020 00:19:47
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-08T17:28:56', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '244d84c4-29ad-4d65-81a8-a23930220c82'	System	09 Sep 2020 00:29:18
User entered 'None (0)'	System	09 Sep 2020 00:29:18

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-08T17:28:57', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '244d84c4-29ad-4d65-81a8-a23930220c82'	System	09 Sep 2020 00:29:18
User entered 'None (0)'	System	09 Sep 2020 00:29:18

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-08T17:29:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '244d84c4-29ad-4d65-81a8-a23930220c82'	System	09 Sep 2020 00:29:18
User entered 'None (0)'	System	09 Sep 2020 00:29:18

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-08T17:29:02', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '244d84c4-29ad-4d65-81a8-a23930220c82'	System	09 Sep 2020 00:29:18
User entered 'None (0)'	System	09 Sep 2020 00:29:18

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-08T17:29:04', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '244d84c4-29ad-4d65-81a8-a23930220c82'	System	09 Sep 2020 00:29:18
User entered 'None (0)'	System	09 Sep 2020 00:29:18

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-08T17:29:05', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '244d84c4-29ad-4d65-81a8-a23930220c82'	System	09 Sep 2020 00:29:18
User entered 'None (0)'	System	09 Sep 2020 00:29:18

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-08T17:29:12', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '244d84c4-29ad-4d65-81a8-a23930220c82'	System	09 Sep 2020 00:29:18
User entered 'No (N)'	System	09 Sep 2020 00:29:18



US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-08T17:29:15', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '244d84c4-29ad-4d65-81a8-a23930220c82'	System	09 Sep 2020 00:29:18
User entered '08 Sep 2020 17:29'	System	09 Sep 2020 00:29:18

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:46:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '08 Sep 2020 17:14'	System	09 Sep 2020 00:19:47

**US3772007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '08 Sep 2020 19:44'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	09 Sep 2020 00:19:47
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-09T08:41:19', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '28d909aa-779a-4bab-9cc2-a05e36163755'	System	09 Sep 2020 15:41:41
User entered 'None (0)'	System	09 Sep 2020 15:41:41

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-09T08:41:24', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '28d909aa-779a-4bab-9cc2-a05e36163755'	System	09 Sep 2020 15:41:41
User entered 'None (0)'	System	09 Sep 2020 15:41:41

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-09T08:41:26', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '28d909aa-779a-4bab-9cc2-a05e36163755'	System	09 Sep 2020 15:41:41
User entered 'None (0)'	System	09 Sep 2020 15:41:41

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-09T08:41:28', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '28d909aa-779a-4bab-9cc2-a05e36163755'	System	09 Sep 2020 15:41:41
User entered 'None (0)'	System	09 Sep 2020 15:41:41



US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-09T08:41:29', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '28d909aa-779a-4bab-9cc2-a05e36163755'	System	09 Sep 2020 15:41:41
User entered 'None (0)'	System	09 Sep 2020 15:41:41

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-09T08:41:31', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '28d909aa-779a-4bab-9cc2-a05e36163755'	System	09 Sep 2020 15:41:41
User entered 'None (0)'	System	09 Sep 2020 15:41:41

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-09T08:41:38', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '28d909aa-779a-4bab-9cc2-a05e36163755'	System	09 Sep 2020 15:41:41
User entered 'No (N)'	System	09 Sep 2020 15:41:41

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-09T08:41:40', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '28d909aa-779a-4bab-9cc2-a05e36163755'	System	09 Sep 2020 15:41:41
User entered '09 Sep 2020 08:41'	System	09 Sep 2020 15:41:41

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '08 Sep 2020 20:39'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:46:07

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '09 Sep 2020 11:59'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	09 Sep 2020 00:19:47
User entered 'Day 2'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:46:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-09T22:38:15', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '8c6cbdea-47bf-4f33-9407-18e62831ed92'	System	10 Sep 2020 05:38:30
User entered 'None (0)'	System	10 Sep 2020 05:38:30



US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:46:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-09T22:38:16', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '8c6cbdea-47bf-4f33-9407-18e62831ed92'	System	10 Sep 2020 05:38:30
User entered 'None (0)'	System	10 Sep 2020 05:38:30

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:46:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-09T22:38:17', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '8c6cbdea-47bf-4f33-9407-18e62831ed92'	System	10 Sep 2020 05:38:30
User entered 'None (0)'	System	10 Sep 2020 05:38:30

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:46:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-09T22:38:19', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '8c6cbdea-47bf-4f33-9407-18e62831ed92'	System	10 Sep 2020 05:38:30
User entered 'None (0)'	System	10 Sep 2020 05:38:30

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:46:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-09T22:38:21', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '8c6cbdea-47bf-4f33-9407-18e62831ed92'	System	10 Sep 2020 05:38:30
User entered 'None (0)'	System	10 Sep 2020 05:38:30

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:46:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-09T22:38:22', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '8c6cbdea-47bf-4f33-9407-18e62831ed92'	System	10 Sep 2020 05:38:30
User entered 'None (0)'	System	10 Sep 2020 05:38:30

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-09T22:38:25', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '8c6cbdea-47bf-4f33-9407-18e62831ed92'	System	10 Sep 2020 05:38:30
User entered 'No (N)'	System	10 Sep 2020 05:38:30

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:46:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-09T22:38:27', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '8c6cbdea-47bf-4f33-9407-18e62831ed92'	System	10 Sep 2020 05:38:30
User entered '09 Sep 2020 22:38'	System	10 Sep 2020 05:38:30

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:46:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '09 Sep 2020 12:00'	System	09 Sep 2020 00:19:47



**US3772007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	09 Sep 2020 00:19:47
User entered 'Day 3'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:46:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-10T15:53:10', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'e59c7693-4d26-4ea1-a3f2-25cdc4de7ebe' User entered 'None (0)'	System	10 Sep 2020 22:53:45
	System	10 Sep 2020 22:53:45

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:46:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-10T15:53:12', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'e59c7693-4d26-4ea1-a3f2-25cdc4de7ebe'	System	10 Sep 2020 22:53:45
User entered 'None (0)'	System	10 Sep 2020 22:53:45

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:46:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-10T15:53:13', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'e59c7693-4d26-4ea1-a3f2-25cdc4de7ebe' User entered 'None (0)'	System	10 Sep 2020 22:53:45
	System	10 Sep 2020 22:53:45

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:46:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-10T15:53:15', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'e59c7693-4d26-4ea1-a3f2-25cdc4de7ebe' User entered 'None (0)'	System	10 Sep 2020 22:53:45
	System	10 Sep 2020 22:53:45

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:46:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-10T15:53:16', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'e59c7693-4d26-4ea1-a3f2-25cdc4de7ebe'	System	10 Sep 2020 22:53:45
User entered 'None (0)'	System	10 Sep 2020 22:53:45

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:46:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-10T15:53:22', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'e59c7693-4d26-4ea1-a3f2-25cdc4de7ebe' User entered 'None (0)'	System	10 Sep 2020 22:53:45
	System	10 Sep 2020 22:53:45



US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-10T15:53:24', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'e59c7693-4d26-4ea1-a3f2-25cdc4de7ebe'	System	10 Sep 2020 22:53:45
User entered 'No (N)'	System	10 Sep 2020 22:53:45

**US3772007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-10T15:53:43', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'e59c7693-4d26-4ea1-a3f2-25cdc4de7ebe' User entered '10 Sep 2020 15:53'	System	10 Sep 2020 22:53:45
	System	10 Sep 2020 22:53:45

**US3772007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 00:19:47

**US3772007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	09 Sep 2020 00:19:47
User entered 'Day 4'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:46:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:46:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:46:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20



US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:46:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:46:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:46:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:46:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:46:07

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 00:19:47

**US3772007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	09 Sep 2020 00:19:47
User entered 'Day 5'	System	09 Sep 2020 00:19:47



US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:46:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-12T23:52:38', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '7baac9a2-1c5d-48a1-b9c4-28bb3fdf71af'	System	13 Sep 2020 06:53:23
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	13 Sep 2020 06:53:23

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:46:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-12T23:52:42', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '7baac9a2-1c5d-48a1-b9c4-28bb3fdf71af'	System	13 Sep 2020 06:53:23
User entered 'None (0)'	System	13 Sep 2020 06:53:23

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:46:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-12T23:52:47', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '7baac9a2-1c5d-48a1-b9c4-28bb3fdf71af'	System	13 Sep 2020 06:53:23
User entered 'No interference with activity (1)'	System	13 Sep 2020 06:53:23

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:46:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-12T23:52:52', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '7baac9a2-1c5d-48a1-b9c4-28bb3fdf71af'	System	13 Sep 2020 06:53:23
User entered 'No interference with activity (1)'	System	13 Sep 2020 06:53:23

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:46:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-12T23:53:11', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '7baac9a2-1c5d-48a1-b9c4-28bb3fdf71af'	System	13 Sep 2020 06:53:23
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	13 Sep 2020 06:53:23

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:46:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-12T23:53:14', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '7baac9a2-1c5d-48a1-b9c4-28bb3fdf71af'	System	13 Sep 2020 06:53:23
User entered 'No interference with activity (1)'	System	13 Sep 2020 06:53:23

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-12T23:53:18', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '7baac9a2-1c5d-48a1-b9c4-28bb3fdf71af'	System	13 Sep 2020 06:53:23
User entered 'No (N)'	System	13 Sep 2020 06:53:23

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:46:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-12T23:53:21', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '7baac9a2-1c5d-48a1-b9c4-28bb3fdf71af'	System	13 Sep 2020 06:53:23
User entered '12 Sep 2020 23:53'	System	13 Sep 2020 06:53:23



**US3772007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 00:19:47

**US3772007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	09 Sep 2020 00:19:47
User entered 'Day 6'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:46:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-14T08:30:57', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '3d2f652f-ccc2-45e4-babf-7afef5d54b4e'	System	14 Sep 2020 15:31:15
User entered 'None (0)'	System	14 Sep 2020 15:31:15

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:46:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-14T08:30:58', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '3d2f652f-ccc2-45e4-babf-7afef5d54b4e'	System	14 Sep 2020 15:31:15
User entered 'None (0)'	System	14 Sep 2020 15:31:15

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:46:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-14T08:31:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '3d2f652f-ccc2-45e4-babf-7afef5d54b4e'	System	14 Sep 2020 15:31:15
User entered 'None (0)'	System	14 Sep 2020 15:31:15

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:46:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-14T08:31:01', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '3d2f652f-ccc2-45e4-babf-7afef5d54b4e'	System	14 Sep 2020 15:31:15
User entered 'None (0)'	System	14 Sep 2020 15:31:15

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:46:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-14T08:31:02', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '3d2f652f-ccc2-45e4-babf-7afef5d54b4e'	System	14 Sep 2020 15:31:15
User entered 'None (0)'	System	14 Sep 2020 15:31:15



US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:46:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-14T08:31:04', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '3d2f652f-ccc2-45e4-babf-7afef5d54b4e'	System	14 Sep 2020 15:31:15
User entered 'None (0)'	System	14 Sep 2020 15:31:15

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-14T08:31:06', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '3d2f652f-ccc2-45e4-babf-7afef5d54b4e'	System	14 Sep 2020 15:31:15
User entered 'No (N)'	System	14 Sep 2020 15:31:15

**US3772007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-14T08:31:10', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '3d2f652f-ccc2-45e4-babf-7afef5d54b4e'	System	14 Sep 2020 15:31:15
User entered '14 Sep 2020 08:31'	System	14 Sep 2020 15:31:15

**US3772007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 00:19:47

**US3772007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	09 Sep 2020 00:19:47
User entered 'Day 7'	System	09 Sep 2020 00:19:47

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:46:07

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-15T08:12:21', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '68397ec1-c3f4-41b0-94b6-35f6739b9f38'	System	15 Sep 2020 15:12:47
User entered 'None (0)'	System	15 Sep 2020 15:12:47

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:46:07

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-15T08:12:23', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '68397ec1-c3f4-41b0-94b6-35f6739b9f38'	System	15 Sep 2020 15:12:47
User entered 'None (0)'	System	15 Sep 2020 15:12:47



US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:46:07

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-15T08:12:28', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '68397ec1-c3f4-41b0-94b6-35f6739b9f38'	System	15 Sep 2020 15:12:47
User entered 'None (0)'	System	15 Sep 2020 15:12:47

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:46:07

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-15T08:12:30', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '68397ec1-c3f4-41b0-94b6-35f6739b9f38'	System	15 Sep 2020 15:12:47
User entered 'None (0)'	System	15 Sep 2020 15:12:47

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:46:07

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-15T08:12:32', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '68397ec1-c3f4-41b0-94b6-35f6739b9f38'	System	15 Sep 2020 15:12:47
User entered 'None (0)'	System	15 Sep 2020 15:12:47

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:46:07

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-15T08:12:34', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '68397ec1-c3f4-41b0-94b6-35f6739b9f38'	System	15 Sep 2020 15:12:47
User entered 'None (0)'	System	15 Sep 2020 15:12:47

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:46:07

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 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-15T08:12:37', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '68397ec1-c3f4-41b0-94b6-35f6739b9f38'	System	15 Sep 2020 15:12:47
User entered 'No (N)'	System	15 Sep 2020 15:12:47

US3772007

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:46:07

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-09-15T08:12:41', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '68397ec1-c3f4-41b0-94b6-35f6739b9f38'	System	15 Sep 2020 15:12:47
User entered '15 Sep 2020 08:12'	System	15 Sep 2020 15:12:47

**US3772007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 00:19:47

**US3772007**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:46:07**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 00:19:47



US3772007

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Yes (Y)'	(b) (4) Marisol Corrales (b) (4)	15 Sep 2020 16:58:48

US3772007

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered '15 Sep 2020'	(b) (4) Marisol Corrales (b) (4)	15 Sep 2020 16:58:48

US3772007

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Marisol Corrales (b) (4)	15 Sep 2020 16:58:48

US3772007

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:07

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered empty.	(b) (4) Marisol Corrales (b) (4)	15 Sep 2020 16:58:48

US3772007

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'Yes (Y)'	(b) (4) Marisol Corrales (b) (4)	15 Sep 2020 16:58:51

**US3772007**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:46:07**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered 'I'	System	15 Sep 2020 16:58:51

US3772007

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	22 Sep 2020 17:26:22

US3772007

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered '22 Sep 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	22 Sep 2020 17:26:22



US3772007

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Emily Crews (b) (4)	22 Sep 2020 17:26:22

US3772007

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:07

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	22 Sep 2020 17:26:22

US3772007

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	22 Sep 2020 17:26:28

**US3772007**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:46:07**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered 'I'	System	22 Sep 2020 17:26:28

US3772007

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 17:17:57

**US3772007**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:46:07**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered '29 Sep 2020'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 17:17:57

US3772007

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 17:17:57

US3772007

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:07

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Sep 2020 17:17:57



US3772007

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Sep 2020 17:18:07

**US3772007**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:46:07**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered 'I'	System	29 Sep 2020 17:18:07

US3772007

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:46:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:02:02
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered 'Yes (Y)'	Matthew Pohlmeier (b) (4)	12 Oct 2020 23:19:24

US3772007

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:02:02
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered '12 Oct 2020'	(b) (4) Matthew Pohlmeier (b) (4)	12 Oct 2020 23:19:24

US3772007

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:02:02
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered 'Clinic (Clinic)'	Matthew Pohlmeier (b) (4)	12 Oct 2020 23:19:24

**US3772007**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:46:07**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:02:02
User entered 'VISIT3'	System	12 Oct 2020 23:19:24

US3772007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:02:02
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered 'Yes (Y)'	Emily Crews (b) (4)	15 Oct 2020 16:13:04

US3772007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:02:02
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered '12 Oct 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Oct 2020 16:13:04



US3772007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:02:02
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered '16:20'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Oct 2020 16:13:04

US3772007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:02:02
User entered '12 Oct 2020 16:20'	System	15 Oct 2020 16:13:04

US3772007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:02:02
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered '36.6' C	Emily Crews (b) (4)	15 Oct 2020 16:13:04

US3772007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:02:02
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered 'Oral (Oral)'	Emily Crews (b) (4)	15 Oct 2020 16:13:04

US3772007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:02:02
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	15 Oct 2020 16:13:04

US3772007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:02:02
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered '70'	Emily Crews (b) (4)	15 Oct 2020 16:13:04

US3772007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:02:02
User entered 'bpm'	System	15 Oct 2020 16:13:04

US3772007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:02:02
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered '14'	Emily Crews (b) (4)	15 Oct 2020 16:13:04



US3772007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:02:02
User entered 'breaths/min'	System	15 Oct 2020 16:13:04

US3772007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:02:02
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered '133'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Oct 2020 16:13:04

US3772007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:02:02
User entered 'mmHg'	System	15 Oct 2020 16:13:04

US3772007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:02:02
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered '87'	Emily Crews (b) (4)	15 Oct 2020 16:13:04

US3772007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:02:02
User entered 'mmHg'	System	15 Oct 2020 16:13:04

US3772007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:02:02

US3772007

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:02:02

US3772007

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:46:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:02:02
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered 'No (N)'	Matthew Pohlmeier (b) (4)	12 Oct 2020 23:19:34



US3772007

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:46:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:02:02
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered empty.	(b) (4) Matthew Pohlmeier (b) (4)	12 Oct 2020 23:19:34

US3772007

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:46:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:02:02
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4)	15 Oct 2020 16:13:27

US3772007

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:46:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:02:02
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered '12 Oct 2020'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Oct 2020 16:13:27

US3772007

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:46:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:02:02
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered '16:30'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Oct 2020 16:13:27

**US3772007**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:46:07**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:02:02
User entered '12 Oct 2020 16:30'	System	15 Oct 2020 16:13:27

US3772007

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered 'Yes (Y)'	(b) (4) Matthew Pohlmeier (b) (4)	12 Oct 2020 23:19:50

US3772007

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered 'I'	System	12 Oct 2020 23:19:50

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17
Data entry locked.	System	05 Aug 2020 16:41:51
User entered 'Day 64'	System	05 Aug 2020 16:41:51



US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

[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 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

Have you been exposed to someone with 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 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Please 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 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

[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 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Please 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 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

[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 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Please 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 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17
Data entry locked.	System	05 Aug 2020 16:41:51
User entered '05 Oct 2020 00:01'	System	05 Aug 2020 16:41:51

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17
Data entry locked.	System	05 Aug 2020 16:41:51
User entered '09 Oct 2020 23:59'	System	05 Aug 2020 16:41:51

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	05 Aug 2020 16:41:51
User entered 'Day 71'	System	05 Aug 2020 16:41:51

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-10-12T16:22:36', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'c13cf306-f301-4264-8d98-1116f5d189a7'	System	12 Oct 2020 23:22:46
User entered 'No (N)'	System	12 Oct 2020 23:22:46

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-10-12T16:22:40', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'c13cf306-f301-4264-8d98-1116f5d189a7'	System	12 Oct 2020 23:22:46
User entered 'No (N)'	System	12 Oct 2020 23:22:46

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-10-12T16:22:43', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'c13cf306-f301-4264-8d98-1116f5d189a7'	System	12 Oct 2020 23:22:46
User entered '12 Oct 2020 16:22:43'	System	12 Oct 2020 23:22:46

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	05 Aug 2020 16:41:51
User entered '12 Oct 2020 00:01'	System	05 Aug 2020 16:41:51



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	05 Aug 2020 16:41:51
User entered '16 Oct 2020 23:59'	System	05 Aug 2020 16:41:51

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	05 Aug 2020 16:41:51
User entered 'Day 78'	System	05 Aug 2020 16:41:51

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-10-19T08:56:31', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '0b897f10-d7b4-4040-8016-0ea106ef2413'	System	19 Oct 2020 15:56:44
User entered 'No (N)'	System	19 Oct 2020 15:56:44

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-10-19T08:56:34', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '0b897f10-d7b4-4040-8016-0ea106ef2413'	System	19 Oct 2020 15:56:44
User entered 'No (N)'	System	19 Oct 2020 15:56:44

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-10-19T08:56:40', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '0b897f10-d7b4-4040-8016-0ea106ef2413'	System	19 Oct 2020 15:56:44
User entered '19 Oct 2020 08:56:40'	System	19 Oct 2020 15:56:44

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	05 Aug 2020 16:41:51
User entered '19 Oct 2020 00:01'	System	05 Aug 2020 16:41:51

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	05 Aug 2020 16:41:51
User entered '23 Oct 2020 23:59'	System	05 Aug 2020 16:41:51

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	05 Aug 2020 16:41:51
User entered 'Day 92'	System	05 Aug 2020 16:41:51



US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-11-02T18:01:49', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '92a99bc0-c30d-41a6-982b-ef30825ffed9'	System	03 Nov 2020 02:01:58
User entered 'No (N)'	System	03 Nov 2020 02:01:58

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-11-02T18:01:51', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '92a99bc0-c30d-41a6-982b-ef30825ffed9'	System	03 Nov 2020 02:01:58
User entered 'No (N)'	System	03 Nov 2020 02:01:58

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-11-02T18:01:54', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '92a99bc0-c30d-41a6-982b-ef30825ffed9'	System	03 Nov 2020 02:01:58
User entered '02 Nov 2020 18:01:54'	System	03 Nov 2020 02:01:58

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	05 Aug 2020 16:41:51
User entered '02 Nov 2020 00:01'	System	05 Aug 2020 16:41:51

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	05 Aug 2020 16:41:51
User entered '06 Nov 2020 23:59'	System	05 Aug 2020 16:41:51

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	05 Aug 2020 16:41:51
User entered 'Day 99'	System	05 Aug 2020 16:41:51

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-11-10T07:30:31', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '5af3bb40-8ac6-4044-bcdb-9204887aef7c'	System	10 Nov 2020 15:30:40
User entered 'No (N)'	System	10 Nov 2020 15:30:40

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-11-10T07:30:33', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '5af3bb40-8ac6-4044-bcdb-9204887aef7c'	System	10 Nov 2020 15:30:40
User entered 'No (N)'	System	10 Nov 2020 15:30:40



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-11-10T07:30:36', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '5af3bb40-8ac6-4044-bcdb-9204887aef7c'	System	10 Nov 2020 15:30:40
User entered '10 Nov 2020 07:30:36'	System	10 Nov 2020 15:30:40

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	05 Aug 2020 16:41:51
User entered '09 Nov 2020 00:01'	System	05 Aug 2020 16:41:51

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:06:20
Data entry locked.	System	05 Aug 2020 16:41:51
User entered '13 Nov 2020 23:59'	System	05 Aug 2020 16:41:51

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17
Data entry locked.	System	05 Aug 2020 16:41:51
User entered 'Day 106'	System	05 Aug 2020 16:41:51

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

[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 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

Have you been exposed to someone with 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 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Please 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 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

[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 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17



US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17



US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Please 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 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

US3772007

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:46:07

[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 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Please 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 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17

**US3772007**

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

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**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17
Data entry locked.	System	05 Aug 2020 16:41:51
User entered '16 Nov 2020 00:01'	System	05 Aug 2020 16:41:51

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:23:17
Data entry locked.	System	05 Aug 2020 16:41:51
User entered '20 Nov 2020 23:59'	System	05 Aug 2020 16:41:51

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 13:23:17



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[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 (eab3bfd0137fa3c7)', Time: '2020-11-23T11:39:08', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '84f858df-7150-4d02-bbf2-62f16dd6e7fa'	System	23 Nov 2020 19:39:16
User entered 'No (N)'	System	23 Nov 2020 19:39:16

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Have you been exposed to someone with 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 (eab3bfd0137fa3c7)', Time: '2020-11-23T11:39:10', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '84f858df-7150-4d02-bbf2-62f16dd6e7fa'	System	23 Nov 2020 19:39:16
User entered 'No (N)'	System	23 Nov 2020 19:39:16

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-11-23T11:39:13', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '84f858df-7150-4d02-bbf2-62f16dd6e7fa'	System	23 Nov 2020 19:39:16
User entered '23 Nov 2020 11:39:13'	System	23 Nov 2020 19:39:16

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 13:23:17



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[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 (eab3bfd0137fa3c7)', Time: '2020-12-07T09:53:11', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'e6c1e142-b4c7-4796-ada7-baddb4b63685'	System	07 Dec 2020 17:53:23
User entered 'No (N)'	System	07 Dec 2020 17:53:23

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Have you been exposed to someone with 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 (eab3bfd0137fa3c7)', Time: '2020-12-07T09:53:14', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'e6c1e142-b4c7-4796-ada7-baddb4b63685'	System	07 Dec 2020 17:53:23
User entered 'No (N)'	System	07 Dec 2020 17:53:23

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-12-07T09:53:17', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'e6c1e142-b4c7-4796-ada7-baddb4b63685' User entered '07 Dec 2020 09:53:17'	System	07 Dec 2020 17:53:23
	System	07 Dec 2020 17:53:23

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[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 (eab3bfd0137fa3c7)', Time: '2020-12-12T20:48:38', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '21834ab2-3d62-4f25-a5e1-8da41df82e68'	System	13 Dec 2020 04:48:47
User entered 'No (N)'	System	13 Dec 2020 04:48:47



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Have you been exposed to someone with 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 (eab3bfd0137fa3c7)', Time: '2020-12-12T20:48:41', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '21834ab2-3d62-4f25-a5e1-8da41df82e68'	System	13 Dec 2020 04:48:47
User entered 'No (N)'	System	13 Dec 2020 04:48:47

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-12-12T20:48:44', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '21834ab2-3d62-4f25-a5e1-8da41df82e68'	System	13 Dec 2020 04:48:47
User entered '12 Dec 2020 20:48:44'	System	13 Dec 2020 04:48:47

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[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 (eab3bfd0137fa3c7)', Time: '2020-12-21T20:13:47', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'b47b74c3-3dc0-423b-a990-5d928fdbfd64'	System	22 Dec 2020 04:13:57
User entered 'No (N)'	System	22 Dec 2020 04:13:57

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

Have you been exposed to someone with 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 (eab3bfd0137fa3c7)', Time: '2020-12-21T20:13:49', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'b47b74c3-3dc0-423b-a990-5d928fdbfd64'	System	22 Dec 2020 04:13:57
User entered 'No (N)'	System	22 Dec 2020 04:13:57

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-12-21T20:13:51', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'b47b74c3-3dc0-423b-a990-5d928fdbfd64'	System	22 Dec 2020 04:13:57
User entered '21 Dec 2020 20:13:51'	System	22 Dec 2020 04:13:57



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[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 (eab3bfd0137fa3c7)', Time: '2020-12-29T11:09:42', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'a99c62f7-02df-4b87-ab01-d7a469a6c7a6'	System	29 Dec 2020 19:09:52
User entered 'No (N)'	System	29 Dec 2020 19:09:52

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Have you been exposed to someone with 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 (eab3bfd0137fa3c7)', Time: '2020-12-29T11:09:44', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'a99c62f7-02df-4b87-ab01-d7a469a6c7a6'	System	29 Dec 2020 19:09:52
User entered 'No (N)'	System	29 Dec 2020 19:09:52

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2020-12-29T11:09:47', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'a99c62f7-02df-4b87-ab01-d7a469a6c7a6'	System	29 Dec 2020 19:09:52
User entered '29 Dec 2020 11:09:47'	System	29 Dec 2020 19:09:52

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 13:23:17



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[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 (eab3bfd0137fa3c7)', Time: '2021-01-04T12:27:26', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'b126fba1-3f3b-47e3-92e6-6e47d1656df8'	System	04 Jan 2021 20:27:35
User entered 'No (N)'	System	04 Jan 2021 20:27:35

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

Have you been exposed to someone with 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 (eab3bfd0137fa3c7)', Time: '2021-01-04T12:27:30', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'b126fba1-3f3b-47e3-92e6-6e47d1656df8'	System	04 Jan 2021 20:27:35
User entered 'No (N)'	System	04 Jan 2021 20:27:35

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2021-01-04T12:27:32', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'b126fba1-3f3b-47e3-92e6-6e47d1656df8'	System	04 Jan 2021 20:27:35
User entered '04 Jan 2021 12:27:32'	System	04 Jan 2021 20:27:35

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[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 (eab3bfd0137fa3c7)', Time: '2021-01-11T07:46:32', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '4214cb79-f11e-47d8-a072-8e278424532e'	System	11 Jan 2021 15:46:50
User entered 'No (N)'	System	11 Jan 2021 15:46:50



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

Have you been exposed to someone with 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 (eab3bfd0137fa3c7)', Time: '2021-01-11T07:46:35', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '4214cb79-f11e-47d8-a072-8e278424532e'	System	11 Jan 2021 15:46:50
User entered 'No (N)'	System	11 Jan 2021 15:46:50

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2021-01-11T07:46:44', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '4214cb79-f11e-47d8-a072-8e278424532e' User entered '11 Jan 2021 07:46:44'	System	11 Jan 2021 15:46:50
	System	11 Jan 2021 15:46:50

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[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 (eab3bfd0137fa3c7)', Time: '2021-01-19T10:43:11', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '11fba47a-86f8-427c-b307-357771ea5633'	System	19 Jan 2021 18:43:20
User entered 'No (N)'	System	19 Jan 2021 18:43:20

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Have you been exposed to someone with 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 (eab3bfd0137fa3c7)', Time: '2021-01-19T10:43:13', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '11fba47a-86f8-427c-b307-357771ea5633'	System	19 Jan 2021 18:43:20
User entered 'No (N)'	System	19 Jan 2021 18:43:20

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2021-01-19T10:43:16', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '11fba47a-86f8-427c-b307-357771ea5633'	System	19 Jan 2021 18:43:20
User entered '19 Jan 2021 10:43:16'	System	19 Jan 2021 18:43:20



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[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 (eab3bfd0137fa3c7)', Time: '2021-01-22T02:31:55', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'bbaff7c-6a1c-4fc7-b128-eaa7d56e7cd6'	System	22 Jan 2021 10:32:06
User entered 'No (N)'	System	22 Jan 2021 10:32:06

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

Have you been exposed to someone with 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 (eab3bfd0137fa3c7)', Time: '2021-01-22T02:31:58', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'bbaff7c-6a1c-4fc7-b128-eaa7d56e7cd6'	System	22 Jan 2021 10:32:06
User entered 'No (N)'	System	22 Jan 2021 10:32:06

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2021-01-22T02:32:04', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'bbaff7c-6a1c-4fc7-b128-eea7d56e7cd6'	System	22 Jan 2021 10:32:06
User entered '22 Jan 2021 02:32:04'	System	22 Jan 2021 10:32:06

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 13:23:17



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[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 (eab3bfd0137fa3c7)', Time: '2021-01-30T08:10:23', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '360a3014-4a36-4a59-83a0-9844e819bbbd'	System	30 Jan 2021 16:10:32
User entered 'No (N)'	System	30 Jan 2021 16:10:32

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

Have you been exposed to someone with 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 (eab3bfd0137fa3c7)', Time: '2021-01-30T08:10:26', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '360a3014-4a36-4a59-83a0-9844e819bbbd'	System	30 Jan 2021 16:10:32
User entered 'No (N)'	System	30 Jan 2021 16:10:32

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2021-01-30T08:10:28', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '360a3014-4a36-4a59-83a0-9844e819bbbd' User entered '30 Jan 2021 08:10:28'	System	30 Jan 2021 16:10:32
	System	30 Jan 2021 16:10:32

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[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 (eab3bfd0137fa3c7)', Time: '2021-02-05T08:25:54', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'b43dd302-1746-4045-ac9b-d6afd3f70607'	System	05 Feb 2021 16:26:04
User entered 'No (N)'	System	05 Feb 2021 16:26:04



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Have you been exposed to someone with 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 (eab3bfd0137fa3c7)', Time: '2021-02-05T08:25:58', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'b43dd302-1746-4045-ac9b-d6afd3f70607'	System	05 Feb 2021 16:26:04
User entered 'No (N)'	System	05 Feb 2021 16:26:04

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2021-02-05T08:26:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'b43dd302-1746-4045-ac9b-d6afd3f70607'	System	05 Feb 2021 16:26:04
User entered '05 Feb 2021 08:26:00'	System	05 Feb 2021 16:26:04

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[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 (eab3bfd0137fa3c7)', Time: '2021-02-13T19:10:28', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'e0d845dd-5dba-4c7c-9a44-dc760f938f2c'	System	14 Feb 2021 03:10:53
User entered 'Yes (Y)'	System	14 Feb 2021 03:10:53

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

Have you been exposed to someone with 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 (eab3bfd0137fa3c7)', Time: '2021-02-13T19:10:31', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'e0d845dd-5dba-4c7c-9a44-dc760f938f2c'	System	14 Feb 2021 03:10:53
User entered 'No (N)'	System	14 Feb 2021 03:10:53

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[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 (eab3bfd0137fa3c7)', Time: '2021-02-13T19:10:34', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'e0d845dd-5dba-4c7c-9a44-dc760f938f2c'	System	14 Feb 2021 03:10:53
User entered 'No (N)'	System	14 Feb 2021 03:10:53



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[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 (eab3bfd0137fa3c7)', Time: '2021-02-13T19:10:39', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'e0d845dd-5dba-4c7c-9a44-dc760f938f2c'	System	14 Feb 2021 03:10:53
User entered 'Yes (Y)'	System	14 Feb 2021 03:10:53

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Please 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 (eab3bfd0137fa3c7)', Time: '2021-02-13T19:10:45', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'e0d845dd-5dba-4c7c-9a44-dc760f938f2c'	System	14 Feb 2021 03:10:53
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Feb 2021 03:10:53

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2021-02-13T19:10:48', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'e0d845dd-5dba-4c7c-9a44-dc760f938f2c'	System	14 Feb 2021 03:10:53
User entered '13 Feb 2021 19:10:48'	System	14 Feb 2021 03:10:53

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[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 (eab3bfd0137fa3c7)', Time: '2021-02-22T11:59:06', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '51fdbb95-2764-4083-a7f1-99231619bfb0'	System	22 Feb 2021 19:59:15
User entered 'No (N)'	System	22 Feb 2021 19:59:15

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Have you been exposed to someone with 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 (eab3bfd0137fa3c7)', Time: '2021-02-22T11:59:08', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '51fdbb95-2764-4083-a7f1-99231619bfb0'	System	22 Feb 2021 19:59:15
User entered 'No (N)'	System	22 Feb 2021 19:59:15



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2021-02-22T11:59:11', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '51fdbb95-2764-4083-a7f1-99231619bfb0'	System	22 Feb 2021 19:59:15
User entered '22 Feb 2021 11:59:11'	System	22 Feb 2021 19:59:15

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[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 (eab3bfd0137fa3c7)', Time: '2021-03-01T12:44:29-08:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '907f76c2-e9b4-4077-b580-77927869c7cc'	System	01 Mar 2021 20:44:37
User entered 'No (N)'	System	01 Mar 2021 20:44:37

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

Have you been exposed to someone with 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 (eab3bfd0137fa3c7)', Time: '2021-03-01T12:44:32-08:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '907f76c2-e9b4-4077-b580-77927869c7cc'	System	01 Mar 2021 20:44:37
User entered 'No (N)'	System	01 Mar 2021 20:44:37

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2021-03-01T12:44:34-08:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '907f76c2-e9b4-4077-b580-77927869c7cc' User entered '01 Mar 2021 12:44:34'	System	01 Mar 2021 20:44:37
	System	01 Mar 2021 20:44:37

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 13:23:17



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[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 (eab3bfd0137fa3c7)', Time: '2021-03-07T15:14:00-08:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'f5bd3fb7-e999-4854-bc11-a39063ce2e9b'	System	07 Mar 2021 23:16:55
User entered 'No (N)'	System	07 Mar 2021 23:16:55

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Have you been exposed to someone with 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 (eab3bfd0137fa3c7)', Time: '2021-03-07T15:14:04-08:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'f5bd3fb7-e999-4854-bc11-a39063ce2e9b'	System	07 Mar 2021 23:16:55
User entered 'No (N)'	System	07 Mar 2021 23:16:55

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2021-03-07T15:14:07-08:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'f5bd3fb7-e999-4854-bc11-a39063ce2e9b'	System	07 Mar 2021 23:16:55
User entered '07 Mar 2021 15:14:07'	System	07 Mar 2021 23:16:55

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 13:23:17



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[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 (eab3bfd0137fa3c7)', Time: '2021-03-12T07:07:42-08:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '2542a03f-e08a-47a4-8da6-824bbad4b85a' User entered 'No (N)'	System	12 Mar 2021 15:07:51
	System	12 Mar 2021 15:07:51

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

Have you been exposed to someone with 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 (eab3bfd0137fa3c7)', Time: '2021-03-12T07:07:45-08:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '2542a03f-e08a-47a4-8da6-824bbad4b85a'	System	12 Mar 2021 15:07:51
User entered 'No (N)'	System	12 Mar 2021 15:07:51

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2021-03-12T07:07:47-08:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '2542a03f-e08a-47a4-8da6-824bbad4b85a' User entered '12 Mar 2021 07:07:47'	System	12 Mar 2021 15:07:51
	System	12 Mar 2021 15:07:51

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[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 (eab3bfd0137fa3c7)', Time: '2021-03-19T10:46:07-07:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '24f8839a-42eb-4348-81af-b22ff37fdc98'	System	19 Mar 2021 17:46:18
User entered 'No (N)'	System	19 Mar 2021 17:46:18

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Have you been exposed to someone with 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 (eab3bfd0137fa3c7)', Time: '2021-03-19T10:46:09-07:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '24f8839a-42eb-4348-81af-b22ff37fdc98'	System	19 Mar 2021 17:46:18
User entered 'No (N)'	System	19 Mar 2021 17:46:18



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2021-03-19T10:46:11-07:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '24f8839a-42eb-4348-81af-b22ff37fdc98'	System	19 Mar 2021 17:46:18
User entered '19 Mar 2021 10:46:11'	System	19 Mar 2021 17:46:18

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[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 (73222a1c166ea5bd)', Time: '2021-03-29T15:51:39-07:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'b281a9ca-e490-4b95-8998-06708d666200'	System	29 Mar 2021 22:51:50
User entered 'No (N)'	System	29 Mar 2021 22:51:50

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

Have you been exposed to someone with 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 (73222a1c166ea5bd)', Time: '2021-03-29T15:51:41-07:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'b281a9ca-e490-4b95-8998-06708d666200'	System	29 Mar 2021 22:51:50
User entered 'No (N)'	System	29 Mar 2021 22:51:50

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (73222a1c166ea5bd)', Time: '2021-03-29T15:51:44-07:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'b281a9ca-e490-4b95-8998-06708d666200'	System	29 Mar 2021 22:51:50
User entered '29 Mar 2021 15:51:44'	System	29 Mar 2021 22:51:50

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 13:23:17



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[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 (73222a1c166ea5bd)', Time: '2021-04-02T00:15:09-07:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '8168747e-c647-4c17-830c-421e18df62fd' User entered 'No (N)'	System	02 Apr 2021 07:15:20
	System	02 Apr 2021 07:15:20

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

Have you been exposed to someone with 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 (73222a1c166ea5bd)', Time: '2021-04-02T00:15:12-07:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '8168747e-c647-4c17-830c-421e18df62fd' User entered 'No (N)'	System	02 Apr 2021 07:15:20
	System	02 Apr 2021 07:15:20

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (73222a1c166ea5bd)', Time: '2021-04-02T00:15:15-07:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '8168747e-c647-4c17-830c-421e18df62fd' User entered '02 Apr 2021 00:15:15'	System	02 Apr 2021 07:15:20
	System	02 Apr 2021 07:15:20

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 13:23:17



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[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 (73222a1c166ea5bd)', Time: '2021-04-12T11:55:17-07:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'abb15c5f-7967-4b08-9252-138495c9082f' User entered 'No (N)'	System	12 Apr 2021 18:55:23
	System	12 Apr 2021 18:55:23

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

Have you been exposed to someone with 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 (73222a1c166ea5bd)', Time: '2021-04-12T11:55:19-07:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'abb15c5f-7967-4b08-9252-138495c9082f' User entered 'No (N)'	System	12 Apr 2021 18:55:23
	System	12 Apr 2021 18:55:23

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (73222a1c166ea5bd)', Time: '2021-04-12T11:55:21-07:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'abb15c5f-7967-4b08-9252-138495c9082f' User entered '12 Apr 2021 11:55:21'	System	12 Apr 2021 18:55:23
	System	12 Apr 2021 18:55:23

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[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 (73222a1c166ea5bd)', Time: '2021-04-17T10:10:16-07:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '301400d0-a8c5-4ce5-b54f-e6d279e4db23' User entered 'No (N)'	System	17 Apr 2021 17:10:26
	System	17 Apr 2021 17:10:26

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

Have you been exposed to someone with 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 (73222a1c166ea5bd)', Time: '2021-04-17T10:10:19-07:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '301400d0-a8c5-4ce5-b54f-e6d279e4db23'	System	17 Apr 2021 17:10:26
User entered 'No (N)'	System	17 Apr 2021 17:10:26



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (73222a1c166ea5bd)', Time: '2021-04-17T10:10:22-07:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '301400d0-a8c5-4ce5-b54f-e6d279e4db23' User entered '17 Apr 2021 10:10:22'	System	17 Apr 2021 17:10:26
	System	17 Apr 2021 17:10:26

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[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 (73222a1c166ea5bd)', Time: '2021-04-23T11:23:58-07:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '4b328f78-5aa5-4257-8afe-0fdaa3ce493b' User entered 'No (N)'	System	23 Apr 2021 18:24:09
	System	23 Apr 2021 18:24:09

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

Have you been exposed to someone with 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 (73222a1c166ea5bd)', Time: '2021-04-23T11:24:01-07:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '4b328f78-5aa5-4257-8afe-0fdaa3ce493b'	System	23 Apr 2021 18:24:09
User entered 'No (N)'	System	23 Apr 2021 18:24:09

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (73222a1c166ea5bd)', Time: '2021-04-23T11:24:04-07:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: '4b328f78-5aa5-4257-8afe-0fdaa3ce493b'	System	23 Apr 2021 18:24:09
User entered '23 Apr 2021 11:24:04'	System	23 Apr 2021 18:24:09

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 13:23:17



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[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 (73222a1c166ea5bd)', Time: '2021-04-30T08:59:33-07:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'ab7fa88f-6c5d-4bec-a014-c9311c6c02e7'	System	30 Apr 2021 16:00:17
User entered 'No (N)'	System	30 Apr 2021 16:00:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

Have you been exposed to someone with 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 (73222a1c166ea5bd)', Time: '2021-04-30T08:59:35-07:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'ab7fa88f-6c5d-4bec-a014-c9311c6c02e7'	System	30 Apr 2021 16:00:17
User entered 'No (N)'	System	30 Apr 2021 16:00:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (73222a1c166ea5bd)', Time: '2021-04-30T08:59:37-07:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'ab7fa88f-6c5d-4bec-a014-c9311c6c02e7'	System	30 Apr 2021 16:00:17
User entered '30 Apr 2021 08:59:37'	System	30 Apr 2021 16:00:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 13:23:17



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 13:23:17



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 13:23:17



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 13:23:17



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 13:23:17



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 13:23:17



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 13:23:17



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 13:23:17



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 13:23:17



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 13:23:17



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 13:23:17



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 13:23:17



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 13:23:17



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 13:23:17



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 13:23:17



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 13:23:17



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 13:23:17



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 13:23:17



**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 13:23:17



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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 13:23:17



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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 13:23:17

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 13:23:17

**US3772007**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 13:23:17



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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 13:23:17

**US3772007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 13:23:17

**US3772007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 13:23:17



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 13:23:17

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 13:23:17

**US3772007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 13:23:17

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 13:23:17

**US3772007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 13:23:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 13:23:17



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 13:23:17

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 13:23:17

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 13:23:17

**US3772007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 13:23:17

**US3772007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 13:23:17



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 13:23:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 13:23:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 13:23:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 13:23:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 13:23:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 13:23:17



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 13:23:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 13:23:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 13:23:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 13:23:17

**US3772007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 13:23:17

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 13:23:17



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**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 13:23:17

**US3772007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 13:23:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 13:23:17

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 13:23:17

**US3772007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 13:23:17

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 13:23:17



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 13:23:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 13:23:17

**US3772007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 13:23:17

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 13:23:17

**US3772007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 13:23:17



**US3772007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 13:23:17

**US3772007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 13:23:17

**US3772007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 13:23:17

**US3772007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 13:23:17

**US3772007**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:46:07**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 13:23:17
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 13:23:17



US3772007

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:46:07

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 14:09:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2021-03-01T12:44:39-08:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'e5178d36-3ccd-4378-b0d6-97b6c3a3f44b' User entered 'No (N)'	System	01 Mar 2021 20:44:45
	System	01 Mar 2021 20:44:45

**US3772007**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:46:07**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:09:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (eab3bfd0137fa3c7)', Time: '2021-03-01T12:44:42-08:00', User OID: 'PatientReportedOutcome (US3772007)', ODM File OID: 'e5178d36-3ccd-4378-b0d6-97b6c3a3f44b' User entered '01 Mar 2021 12:44:42'	System	01 Mar 2021 20:44:45
	System	01 Mar 2021 20:44:45

**US3772007**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:46:07**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Nov 2020 22:14:26

**US3772007**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:46:07**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered '2 Nov 2020'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:14:26

US3772007

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:14:26

US3772007

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:07

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:14:26

US3772007

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:14:31

**US3772007**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:46:07**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:01:40
User entered 'I'	System	02 Nov 2020 22:14:31



**US3772007**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:46:07**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:17:47
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:04:50
User entered 'Yes (Y)'	Ruba Zanaid (b) (4) (b) (4)	07 Dec 2020 22:20:36

**US3772007**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:46:07**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:17:47
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:04:50
User entered '7 Dec 2020'	Ruba Zanaid (b) (4) (b) (4)	07 Dec 2020 22:20:36

US3772007

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:17:47
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:04:50
User entered 'Contact Made (CONTACT MADE)'	Ruba Zanaid (b) (4) (b) (4)	07 Dec 2020 22:20:36

US3772007

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:07

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:17:47
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:04:50
User entered empty.	Ruba Zanaid (b) (4) (b) (4)	07 Dec 2020 22:20:36

US3772007

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:17:47
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 18:04:57
User entered 'Yes (Y)'	Ruba Zanaid (b) (4) (b) (4)	07 Dec 2020 22:20:42

US3772007

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:17:47
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
User entered 'I'	System	07 Dec 2020 22:20:42

US3772007

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:17:47
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'Yes (Y)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	04 Jan 2021 20:27:00

US3772007

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:07

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:17:47
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered '04 Jan 2021'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	04 Jan 2021 20:27:00



US3772007

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:07

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:17:47
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	04 Jan 2021 20:27:00

US3772007

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:07

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:17:47
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered empty.	(b) (4) Sarah Sandberg (b) (4) (b) (4)	04 Jan 2021 20:27:00

US3772007

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:17:47
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'Yes (Y)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	04 Jan 2021 20:27:04

US3772007

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:07

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:17:47
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
User entered 'I'	System	04 Jan 2021 20:27:04

US3772007

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:17:47
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered 'Yes (Y)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	02 Feb 2021 22:30:36

US3772007

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:07

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:17:47
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered '2 Feb 2021'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	02 Feb 2021 22:30:36

**US3772007**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:46:07**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:17:47
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	02 Feb 2021 22:30:36

US3772007

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:07

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:17:47
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered empty.	(b) (4) Ruba Zanaid (b) (4) (b) (4)	02 Feb 2021 22:30:36



US3772007

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:17:47
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:34:04
User entered 'Yes (Y)'	(b) (4) Ruba Zanaid (b) (4) (b) (4)	02 Feb 2021 22:30:41

**US3772007**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:46:07**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:17:47
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
User entered 'I'	System	02 Feb 2021 22:30:41

**US3772007**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:46:07**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:56:50
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:51:16
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Mar 2021 22:41:07

**US3772007**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:46:07**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:56:50
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:51:16
User entered '12 Mar 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Mar 2021 22:41:07

US3772007

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:46:07

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:56:50
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:51:16
User entered 'Clinic (Clinic)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Mar 2021 22:41:07

**US3772007**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:46:07**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
User entered 'VISIT4'	System	12 Mar 2021 22:41:07

US3772007

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:56:55
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:29:48
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:19:52

US3772007

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:56:55
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:29:48
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:19:52



**US3772007**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:46:07**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:56:55
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:29:48
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:19:52

US3772007

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
User entered empty.	System	01 Apr 2021 21:19:52

US3772007

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:56:55
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:29:48
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:19:52

US3772007

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:56:55
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:29:48
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:19:52

US3772007

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:56:55
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:29:48
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:19:52

**US3772007**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:46:07**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:56:55
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:29:48
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:19:52

**US3772007**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:46:07**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
User entered empty.	System	01 Apr 2021 21:19:52

US3772007

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:56:55
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:29:48
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:19:52



US3772007

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
User entered empty.	System	01 Apr 2021 21:19:52

US3772007

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:56:55
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:29:48
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:19:52

US3772007

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
User entered empty.	System	01 Apr 2021 21:19:52

US3772007

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:56:55
User signature succeeded.	Jamshid Saleh (b) (4)	02 Apr 2021 02:29:48
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	01 Apr 2021 21:19:52

US3772007

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
User entered empty.	System	01 Apr 2021 21:19:52

**US3772007**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:46:07**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45

US3772007

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:46:07

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45

US3772007

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:46:07

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:57:02
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:51:16
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Mar 2021 22:41:12



US3772007

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:46:07

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:57:02
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:51:16
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	12 Mar 2021 22:41:12

US3772007

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:46:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:57:10
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:51:16
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Mar 2021 22:41:42

US3772007

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:46:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:57:10
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:51:16
User entered '12 Mar 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Mar 2021 22:41:42

US3772007

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:46:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:57:10
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:51:16
User entered '14:27'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Mar 2021 22:41:42

**US3772007**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:46:07**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
User entered '12 Mar 2021 14:27'	System	12 Mar 2021 22:41:42

US3772007

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:57:16
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:51:16
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Mar 2021 22:41:48

**US3772007**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:46:07**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:20:10
Data entry locked.	(b) (4), (b) (6)	15 Apr 2021 06:15:45
User entered 'I'	System	12 Mar 2021 22:41:48

US3772007

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:43:51
	(b) (4)	
User entered 'Yes (Y)'	Sarah Sandberg (b) (4)	05 Apr 2021 19:15:47
	(b) (4)	



US3772007

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:43:51
	(b) (4)	
User entered '05 Apr 2021'	Sarah Sandberg (b) (4)	05 Apr 2021 19:15:47
	(b) (4)	

**US3772007**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:46:07**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:43:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sarah Sandberg (b) (4) (b) (4)	05 Apr 2021 19:15:47

US3772007

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:07

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:43:51
User entered empty.	(b) (4) Sarah Sandberg (b) (4)	05 Apr 2021 19:15:47
	(b) (4)	

US3772007

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	15 Apr 2021 19:43:51
	(b) (4)	
User entered 'Yes (Y)'	Sarah Sandberg (b) (4)	05 Apr 2021 19:15:51
	(b) (4)	

**US3772007**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:46:07**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 19:15:51

US3772007

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:07

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	03 May 2021 19:24:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 May 2021 18:06:16

US3772007

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:07

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	03 May 2021 19:24:29
User entered '3 May 2021'	(b) (4) (b) (4), (b) (6)	03 May 2021 18:06:16

**US3772007**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:46:07**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	03 May 2021 19:24:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	03 May 2021 18:06:16



US3772007

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:46:07

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	03 May 2021 19:24:29
User entered empty.	(b) (4) (b) (4), (b) (6)	03 May 2021 18:06:16

US3772007

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:46:07

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	03 May 2021 19:24:29
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 May 2021 18:06:22

**US3772007**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:46:07**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 18:06:22

US3772007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:46:07

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:30
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Jan 2021 00:40:55

US3772007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:46:07

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:30
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered '14 Jan 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Jan 2021 00:40:55

US3772007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:46:07

[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 12:31:30
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'Clinic (Clinic)'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Jan 2021 00:40:55

**US3772007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:46:07**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:30
User entered 'UNBLND_DECIDE'	System	15 Jan 2021 00:40:55

US3772007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:46:07

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:30
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered '14 Jan 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Jan 2021 00:41:09



**US3772007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:46:07**

[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 12:31:30
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:51:16
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:31:50

US3772007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:46:07

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:30
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Jan 2021 00:41:09

**US3772007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:46:07**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:30
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:51:16
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:31:50

US3772007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:46:07

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:30
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered '14 Jan 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Jan 2021 00:41:09

US3772007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:46:07

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:30
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'Placebo (Placebo)'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Jan 2021 00:41:09

US3772007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:46:07

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:30
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 11:20:14
User entered 'Placebo (Placebo)'	Emily Crews (b) (4)	15 Jan 2021 00:41:09
	(b) (4)	

US3772007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:46:07

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:30
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 11:20:14
User entered 'Placebo (Placebo)'	Emily Crews (b) (4)	15 Jan 2021 00:41:09
	(b) (4)	

US3772007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:46:07

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:30
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Jan 2021 00:41:09



US3772007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:46:07

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:30
User entered '1'	System	15 Jan 2021 00:41:09

**US3772007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:46:07**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:30
User entered empty.	System	15 Jan 2021 00:41:09

US3772007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:46:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:30
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User closed query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, no immunogenicity sample was received for the Patient Decision Visit / OL-D1 on 14JAN2021. Please clarify if sample was shipped and provide the accession number and tracking detail in the query response box, as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 16:50:42
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, no immunogenicity sample was received for the Patient Decision Visit / OL-D1 on 14JAN2021. Please clarify if sample was shipped and provide the accession number and tracking detail in the query response box, as appropriate.' answered with 'Stored onsite' (Site from DM).	Emily Crews (b) (4) (b) (4)	05 Feb 2021 16:07:42
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, no immunogenicity sample was received for the Patient Decision Visit / OL-D1 on 14JAN2021. Please clarify if sample was shipped and provide the accession number and tracking detail in the query response box, as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 15:14:18
User entered 'Yes (Y)'	Emily Crews (b) (4) (b) (4)	15 Jan 2021 00:41:20

US3772007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:46:07

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:30
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered '14 Jan 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Jan 2021 00:41:20

US3772007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:46:07

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:30
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered '15:04'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Jan 2021 00:41:20

**US3772007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:46:07**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:30
User entered '14 Jan 2021 15:04'	System	15 Jan 2021 00:41:20

US3772007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:46:07

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:30
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Jan 2021 00:41:29

**US3772007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:46:07**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:30
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered '14 Jan 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Jan 2021 00:41:29



US3772007

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:46:07

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:30
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered '15:06'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Jan 2021 00:41:29

**US3772007**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:46:07**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:31:30
User entered '14 Jan 2021 15:06'	System	15 Jan 2021 00:41:29

US3772007

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:46:07

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:46:08
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:56
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:20:58

US3772007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:07

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:42:17

US3772007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:07

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:42:17
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Dental and oral soft tissue infections, PT: Tooth abscess, LLT: Dental abscess - version MedDRA\\23.0.	Coder Import (b) (4)	22 Oct 2020 16:25:32
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Oct 2020 16:25:32
	(b) (4)	
Data point term sent to Coder	System	22 Oct 2020 16:24:41
User entered 'Dental Abscess'	(b) (4), (b) (6)	22 Oct 2020 16:24:40

US3772007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:07

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:42:17
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Oct 2020 16:24:40

US3772007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:42:17
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'No (N)'	(b) (4), (b) (6)	22 Oct 2020 16:24:40

US3772007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:42:17
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:24:40



US3772007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:42:17
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
	(b) (4)	
User entered '24 Sep 2020'	(b) (4), (b) (6)	22 Oct 2020 16:24:40

US3772007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:07

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:42:17
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
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).	(b) (4)	22 Oct 2020 16:25:01
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Oct 2020 16:25:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 16:25:01
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Oct 2020 16:24:40
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	22 Oct 2020 16:24:40
User entered 'un:un' (non-conformant).	(b) (4), (b) (6)	22 Oct 2020 16:24:40

**US3772007**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:46:07**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:42:17
User entered empty.	System	22 Oct 2020 16:25:01
User entered '24 Sep 2020 UN:UN' (non-conformant).	System	22 Oct 2020 16:24:40

US3772007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:07

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:42:17
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	22 Oct 2020 16:24:40

US3772007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:42:17
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered '30 Sep 2020'	(b) (4), (b) (6)	22 Oct 2020 16:24:40

US3772007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:07

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:42:17
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	(b) (4)	22 Oct 2020 16:25:01
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Oct 2020 16:25:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 16:25:01
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Oct 2020 16:24:40
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	22 Oct 2020 16:24:40
User entered 'un:un' (non-conformant).	(b) (4), (b) (6)	22 Oct 2020 16:24:40

**US3772007**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:46:07**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:42:17
User entered empty.	System	22 Oct 2020 16:25:01
User entered '30 Sep 2020 UN:UN' (non-conformant).	System	22 Oct 2020 16:24:40

US3772007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:07

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:42:17
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:24:40



US3772007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:42:17
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'No (N)'	(b) (4), (b) (6)	22 Oct 2020 16:24:40

US3772007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:07

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:42:17
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered '0'	(b) (4), (b) (6)	22 Oct 2020 16:24:40

US3772007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:07

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:42:17
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered '0'	(b) (4), (b) (6)	22 Oct 2020 16:24:40

US3772007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:42:17
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered '0'	(b) (4), (b) (6)	22 Oct 2020 16:24:40

US3772007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:42:17
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 16:24:40

US3772007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:07

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:42:17
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 16:24:40

US3772007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:07

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:42:17
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 16:24:40

US3772007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:42:17
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 16:24:40



US3772007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:42:17
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	22 Oct 2020 16:24:40

US3772007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:42:17
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered '0'	(b) (4), (b) (6)	22 Oct 2020 16:24:40

US3772007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:07

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:42:17
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	22 Oct 2020 16:24:40

US3772007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:42:17
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	22 Oct 2020 16:24:40

US3772007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:42:17
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	22 Oct 2020 16:24:40

US3772007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:07

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:42:17
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
	(b) (4)	
User entered 'None (NONE)'	(b) (4), (b) (6)	22 Oct 2020 16:24:40

US3772007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:07

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:42:17
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered '0'	(b) (4), (b) (6)	22 Oct 2020 16:24:40

US3772007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:42:17
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
	(b) (4)	
User entered 'l'	(b) (4), (b) (6)	22 Oct 2020 16:24:40



US3772007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:07

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:42:17
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered '0'	(b) (4), (b) (6)	22 Oct 2020 16:24:40

US3772007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:07

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:42:17
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	22 Oct 2020 16:24:40

US3772007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:07

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 16:42:17
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 16:24:40

US3772007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:07

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:42:17
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 16:24:40

**US3772007**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:46:07**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:42:17
User entered '0'	System	22 Oct 2020 16:24:40

US3772007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:07

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:42:17
User entered '1'	System	22 Oct 2020 16:24:40

US3772007

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:46:07

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 16:42:17

US3772007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:07

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:21
User entered 'USA-US107-2021-mRNA-1273-P301000009'	System	16 Feb 2021 16:29:17
User entered 'New'	(b) (4), (b) (6)	16 Feb 2021 16:29:17



US3772007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:07

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Invasive ductal breast carcinoma, LLT: Breast ductal carcinoma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Mar 2021 11:14:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Mar 2021 11:14:44
User closed query 'PV Query: Please consider update the event term to cancer type/stage once information becomes available.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 16:21:47
Data point term sent to Coder	System	12 Mar 2021 23:18:01
Query 'PV Query: Please consider update the event term to cancer type/stage once information becomes available.' answered with 'Updated' (Site from Safety).	Emily Crews (b) (4) (b) (4)	12 Mar 2021 23:17:23
Coding entries removed.	Emily Crews (b) (4) (b) (4)	12 Mar 2021 23:17:18
Signature has been broken.	Emily Crews (b) (4) (b) (4)	12 Mar 2021 23:17:18
User entered 'LEFT BREAST Ductal Cell Carcinoma' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	12 Mar 2021 23:17:18
User opened query 'PV Query: Please consider update the event term to cancer type/stage once information becomes available.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 14:39:29
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast neoplasms unspecified malignancy, PT: Breast neoplasm, LLT: Breast neoplasm - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 11:25:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Feb 2021 11:25:01
User signature succeeded.	Jamshid Saleh (b) (4) (b) (4)	16 Feb 2021 20:33:59
Data point term sent to Coder	System	15 Feb 2021 18:11:20
User entered 'Left Breast Tumor'	Emily Crews (b) (4) (b) (4)	15 Feb 2021 18:10:41

**US3772007**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:46:07**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4)	15 Feb 2021 18:10:41

US3772007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:07

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Feb 2021 18:10:41

US3772007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:07

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Feb 2021 18:10:41

US3772007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User closed query 'PV Query: Pathology report states the biopsy was collected on 05 Feb 2021. Please consider updating event start date to reflect discovery of cancer.' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 20:12:16
Query 'PV Query: Pathology report states the biopsy was collected on 05 Feb 2021. Please consider updating event start date to reflect discovery of cancer.' answered with 'updated' (Site from Safety). Signature has been broken.	Emily Crews (b) (4) (b) (4)	30 Mar 2021 17:08:48
User entered '05 Feb 2021' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	30 Mar 2021 17:07:19
User opened query 'PV Query: Pathology report states the biopsy was collected on 05 Feb 2021. Please consider updating event start date to reflect discovery of cancer.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	22 Mar 2021 13:39:50
User entered '09 Feb 2021'	Jamshid Saleh (b) (4) (b) (4) Emily Crews (b) (4) (b) (4)	16 Feb 2021 20:33:59 15 Feb 2021 18:10:41

**US3772007**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:46:07**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	15 Feb 2021 18:10:41

**US3772007**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:46:07**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Feb 2021 18:10:41

**US3772007**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:46:07**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4)	15 Feb 2021 18:10:41



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User opened query 'PV Query: Thank you for your recent response. Please provide the final event end date, when available. Please keep query open until resolution is achieved.'	(b) (4), (b) (6)	08 Apr 2021 17:01:32
' (Site from Safety). User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 12:13:51
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' answered with 'This is not foreseen to resolve until subject gets treatment. I will update this when the subject has received treatment' (Site from Safety).	Emily Crews (b) (4) (b) (4)	05 Apr 2021 18:55:29
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 13:38:44
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 13:38:44

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:07

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' answered with 'This will not resolve until the the treatment procedure occurs' (Site from Safety).	Emily Crews (b) (4) (b) (4)	15 Mar 2021 19:28:33
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	25 Feb 2021 14:40:33
User signature succeeded.	Jamshid Saleh (b) (4) (b) (4)	16 Feb 2021 20:33:59
User entered empty.	Emily Crews (b) (4) (b) (4)	15 Feb 2021 18:10:41

**US3772007**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:46:07**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	15 Feb 2021 18:10:41

**US3772007**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:46:07**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Feb 2021 18:10:41

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:07

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'Grade 4 (Grade 4)'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Feb 2021 18:10:41

US3772007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:07

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4)	15 Feb 2021 18:10:41

**US3772007**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:46:07**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Feb 2021 18:10:41

US3772007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:07

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'I'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Feb 2021 18:10:41



US3772007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:07

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Feb 2021 18:10:41

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:07

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	15 Feb 2021 18:10:41

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:07

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	15 Feb 2021 18:10:41

**US3772007**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:46:07**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	15 Feb 2021 18:10:41

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:07

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	15 Feb 2021 18:10:41

US3772007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:07

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Feb 2021 18:10:41

US3772007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:07

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Feb 2021 18:10:41

US3772007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:07

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Feb 2021 18:10:41



US3772007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:07

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'Not Related (NOT RELATED)'	(b) (4) Emily Crews (b) (4)	15 Feb 2021 18:10:41

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:07

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'Not Related (NOT RELATED)'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Feb 2021 18:10:41

**US3772007**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:46:07**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Emily Crews (b) (4)	15 Feb 2021 18:10:41

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:07

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'I'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Feb 2021 18:10:41

US3772007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 16:21:56
User closed query 'PV Query: Please provide any additional concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 16:21:53
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Subject planning a double mastectomy that has not yet been scheduled' (Site from Safety).	Emily Crews (b) (4) (b) (4)	12 Mar 2021 23:18:48
Query 'PV Query: Please provide any additional concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'Subject had not taken any concomitant medication 30 days prior to onset of SAE and also is not treating this SAE with conmeds' (Site from Safety).	Emily Crews (b) (4) (b) (4)	12 Mar 2021 23:18:31

US3772007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:07

[Concomitant Medication](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' canceled (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 14:40:49
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 14:40:06
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 14:39:55
User opened query 'PV Query: Please provide any additional concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 14:39:44
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Feb 2021 18:10:41

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	15 Feb 2021 18:10:41

US3772007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:07

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User opened query 'PV Query: Thank you for your recent response. Please provide the final event outcome, when available. Please keep query open until resolution is achieved. ' (Site from Safety). User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 17:02:05
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 20:12:19
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' answered with 'Subject is not treating this AE and is awaiting to schedule a procedure, information will be updated when the outcome changes' (Site from Safety).	Emily Crews (b) (4) (b) (4)	30 Mar 2021 17:04:31
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 13:38:23
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 13:38:23



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Folder: Adverse Events

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[Outcome](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' answered with 'This will not resolve until the the treatment procedure occurs' (Site from Safety).	Emily Crews (b) (4) (b) (4)	15 Mar 2021 19:28:37
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	25 Feb 2021 14:40:19
User signature succeeded.	Jamshid Saleh (b) (4) (b) (4)	16 Feb 2021 20:33:59
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Emily Crews (b) (4) (b) (4)	15 Feb 2021 18:10:41

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**Folder: Adverse Events**

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	15 Feb 2021 18:10:41

US3772007

Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:41:31
User closed query 'PV Query: As start date of event was updated to 05 Feb, please also update case narrative section, which stated the subject was diagnosed with breast cancer on 09 Feb. ' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 15:55:12
Query 'PV Query: As start date of event was updated to 05 Feb, please also update case narrative section, which stated the subject was diagnosed with breast cancer on 09 Feb. ' answered with 'Updated' (Site from Safety).	Emily Crews (b) (4) (b) (4)	15 Apr 2021 19:04:17
DataPoint Un-verified.	Emily Crews (b) (4) (b) (4)	15 Apr 2021 19:03:56
User entered 'SUBJECT CALLED SITE AND REPORTED BEING DIAGNOSED WITH BREAST CANCER ON 05 FEB 2021. THE SUBJECT STATED THEY HAVE NOT RECEIVED THE FINAL BIOPSY RESULTS TO INDICATE TYPE/ STAGE OF CANCER AND GRADING OF THE TUMOR. THE TUMOR IS A 3-5 CM MASS IN THE LEFT BREAST, THE SUBJECT DID GET THEIR LEFT ARM BUT RECEIVED PLACEBO AND OPTED NOT TO RECEIVE THE VACCINE. MEDICAL RECORDS HAVE BEEN REQUESTED FOR ADDITIONAL INFORMATION. RECEIPT OF PATHOLOGY REPORT INDICATES THIS IS INVASIVE DUCTAL CELL CARCINOMA IN THE LEFT BREAST. SUBJECT WILL BE SCHEDULING A DOUBLE MASTECTOMY. SUBJECT HAS NOT TAKEN ANY MEDICATION TO TREAT THIS SAE' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	15 Apr 2021 19:03:56
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:08:40
User opened query 'PV Query: As start date of event was updated to 05 Feb, please also update case narrative section, which stated the subject was diagnosed with breast cancer on 09 Feb. ' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 17:01:17

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: When available, please provide date and results of double mastectomy if procedure is performed.' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 20:12:27
User closed query 'Safety MD query: Please explain how the event met the seriousness criterion of life-threatening, specifically how the event caused an immediate risk of death at time of event diagnosis that required immediate medical or surgical intervention to prevent an imminent fatal outcome. Was the subject at immediate risk of death? LT should only be used when subject was at immediate danger of death, and not potentially in danger, should the event could have been more severe. The event could always be serious e.g. medically significant' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 20:12:24
User closed query 'PV Query: Subject is reported to be taking Chantix for smoking cessation. If subject has a history of smoking, please add to subject's medical history including start/stop date and packs per day.' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 20:12:21
Query 'PV Query: Subject is reported to be taking Chantix for smoking cessation. If subject has a history of smoking, please add to subject's medical history including start/stop date and packs per day.' answered with 'Contacted subject Nicotine addiction added to med hx' (Site from Safety).	Emily Crews (b) (4)	30 Mar 2021 17:08:32
Query 'PV Query: When available, please provide date and results of double mastectomy if procedure is performed.' answered with 'Subject has not yet scheduled this procedure but was advised to contact site when procedure is scheduled.' (Site from Safety).	Emily Crews (b) (4)	30 Mar 2021 17:08:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:07

[Narrative](#)

Audit	User	Time (GMT)
Query 'Safety MD query: Please explain how the event met the seriousness criterion of life-threatening, specifically how the event caused an immediate risk of death at time of event diagnosis that required immediate medical or surgical intervention to prevent an imminent fatal outcome. Was the subject at immediate risk of death? LT should only be used when subject was at immediate danger of death, and not potentially in danger, should the event could have been more severe. The event could always be serious e.g. medically significant' answered with 'Indication made as grade 4 per PI since subject did not have a confirmed Dx or grade when this information was given relayed to site. Per PI this could be life threatening' (Site from Safety).	Emily Crews (b) (4)	30 Mar 2021 17:03:33
User opened query 'PV Query: When available, please provide date and results of double mastectomy if procedure is performed.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 19:39:07
User closed query 'PV Query: Please provide any additional treatment information in addition to double mastectomy, as applicable.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 13:07:01
User closed query 'PV Query: When available, please provide date and results of double mastectomy if procedure is performed.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 13:06:58
Query 'PV Query: Please provide any additional treatment information in addition to double mastectomy, as applicable.' answered with 'Subject denies and treatment ' (Site from Safety).	Emily Crews (b) (4)	23 Mar 2021 15:51:38
Query 'PV Query: When available, please provide date and results of double mastectomy if procedure is performed.' answered with 'Will update when provided with more information' (Site from Safety).	Emily Crews (b) (4)	23 Mar 2021 15:51:11

US3772007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:07

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Safety MD query: Please explain how the event met the seriousness criterion of life-threatening, specifically how the event caused an immediate risk of death at time of event diagnosis that required immediate medical or surgical intervention to prevent an imminent fatal outcome. Was the subject at immediate risk of death? LT should only be used when subject was at immediate danger of death, and not potentially in danger, should the event could have been more severe. The event could always be serious e.g. medically significant' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 13:40:47
User opened query 'PV Query: Subject is reported to be taking Chantix for smoking cessation. If subject has a history of smoking, please add to subject's medical history including start/stop date and packs per day.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 13:40:20
User opened query 'PV Query: Please provide any additional treatment information in addition to double mastectomy, as applicable.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 13:39:31
User opened query 'PV Query: When available, please provide date and results of double mastectomy if procedure is performed.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 13:38:58
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 16:22:02
User closed query 'PV Query: Please provide the breast biopsy results once available.' (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 16:21:59
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'pathology report sent' (Site from Safety).	Emily Crews (b) (4) (b) (4)	12 Mar 2021 23:24:00

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:07

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the breast biopsy results once available.' answered with 'pathology report sent' (Site from Safety). Signature has been broken.	Emily Crews (b) (4) (b) (4)	12 Mar 2021 23:23:53
	Emily Crews (b) (4) (b) (4)	12 Mar 2021 23:17:18
User entered 'SUBJECT CALLED SITE AND REPORTED BEING DIAGNOSED WITH BREAST CANCER ON 09 FEB 2021. THE SUBJECT STATED THEY HAVE NOT RECEIVED THE FINAL BIOPSY RESULTS TO INDICATE TYPE/ STAGE OF CANCER AND GRADING OF THE TUMOR. THE TUMOR IS A 3-5 CM MASS IN THE LEFT BREAST, THE SUBJECT DID GET THEIR LEFT ARM BUT RECEIVED PLACEBO AND OPTED NOT TO RECEIVE THE VACCINE. MEDICAL RECORDS HAVE BEEN REQUESTED FOR ADDITIONAL INFORMATION. Receipt of pathology report indicates this is invasive ductal cell carcinoma in the left breast. Subject will be scheduling a double mastectomy. Subject has not taken any medication to treat this SAE' reason for change: Data Entry Error	Emily Crews (b) (4) (b) (4)	12 Mar 2021 23:17:18
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 14:41:14
User opened query 'PV Query: Please provide the breast biopsy results once available.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 14:40:56
User signature succeeded.	Jamshid Saleh (b) (4) (b) (4)	16 Feb 2021 20:33:59

US3772007

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:46:07

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject called site and reported being diagnosed with Breast Cancer on 09 Feb 2021. The subject stated they have not received the final biopsy results to indicate type/ stage of cancer and grading of the tumor. The tumor is a 3-5 cm mass in the left breast, The subject did get their left arm but received Placebo and opted not to receive the vaccine. Medical records have been requested for additional information.'	Emily Crews (b) (4) (b) (4)	15 Feb 2021 18:10:41



**US3772007**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:46:07**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Feb 2021 18:10:41

**US3772007**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:46:07**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Feb 2021 18:10:41

US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:46:07

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 18:46:08
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User closed query 'Per DM CLR: Per Diary Dose 2 Day 5, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM). Query 'Per DM CLR: Per Diary Dose 2 Day 5, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'Subject denied taking medication when contacted regarding this entry' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 13:04:16
User opened query 'Per DM CLR: Per Diary Dose 2 Day 5, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'Subject denied taking medication when contacted regarding this entry' (Site from DM).	Emily Crews (b) (4) (b) (4)	02 Feb 2021 17:22:47
User opened query 'Per DM CLR: Per Diary Dose 2 Day 5, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM). Signature has been broken.	(b) (4), (b) (6)	28 Jan 2021 03:37:40
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 16:17:15
User signature succeeded.	Jamshid Saleh (b) (4)	16 Sep 2020 17:12:00
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	05 Aug 2020 20:54:34

US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:46:07

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:52:22
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	22 Oct 2020 16:26:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 16:26:36
Data point term sent to Coder	System	22 Oct 2020 16:19:26
User entered 'Tramadol'	(b) (4), (b) (6)	22 Oct 2020 16:18:34

US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:46:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:52:22
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'No (N)'	(b) (4), (b) (6)	22 Oct 2020 16:18:34

US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:46:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:52:22
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'Dental Abscess'	(b) (4), (b) (6)	22 Oct 2020 16:18:34

US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:46:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:52:22
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered '50'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:18:34

US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:46:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:52:22
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:18:34



US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:46:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:52:22
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:18:34

US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:46:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:52:22
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:18:34

US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:46:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:52:22
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:18:34

US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:46:07

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:52:22
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:18:34

US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:46:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:52:22
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:18:34

**US3772007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:46:07**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:52:22
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered '25 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:18:34

US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:46:07

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:52:22
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:18:34

**US3772007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:46:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:52:22
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:18:34



**US3772007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:46:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:52:22
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered '6 Oct 2020'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:18:34

US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:46:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:52:22
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:18:34

**US3772007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:46:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:52:22
User entered empty.	System	22 Oct 2020 16:18:34

**US3772007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:46:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:52:22
User entered empty.	System	22 Oct 2020 16:18:34

US3772007

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:46:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:52:22
User entered empty.	System	22 Oct 2020 16:18:34

US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:46:07

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:52:12
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN;CLAVULANIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 16:21:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 16:21:32
Data point term sent to Coder	System	22 Oct 2020 16:20:28
User entered 'Augmentin'	(b) (4), (b) (6)	22 Oct 2020 16:19:42

US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:46:07

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:52:12
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:19:42

US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:46:07

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:52:12
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'Dental Abscess'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:19:42



US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:46:07

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:52:12
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g. 875/125). ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:15:46
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g. 875/125).	Sarah Sandberg (b) (4) (b) (4)	04 Jan 2021 23:12:54
' answered with 'updated' (Site from DM).		
User entered '875/125' reason for change: Data Entry Error	Sarah Sandberg (b) (4) (b) (4)	04 Jan 2021 23:12:49
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g. 875/125).	(b) (4), (b) (6)	02 Jan 2021 18:45:38
' (Site from DM).		
User entered '875'	(b) (4), (b) (6)	22 Oct 2020 16:19:42

US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:46:07

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:52:12
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:19:42

US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:46:07

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:52:12
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:19:42

US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:46:07

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:52:12
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:19:42

US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:46:07

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:52:12
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:19:42

**US3772007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:46:07**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:52:12
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:19:42

US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:46:07

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:52:12
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:19:42

US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:46:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:52:12
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered '25 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:19:42



**US3772007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:46:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:52:12
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:19:42

**US3772007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:46:07**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:52:12
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:19:42

**US3772007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:46:07**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:52:12
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered '6 Oct 2020'	(b) (4) (b) (4), (b) (6)	22 Oct 2020 16:19:42

US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:46:07

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:52:12
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'No (N)'	(b) (4), (b) (6)	22 Oct 2020 16:19:42

**US3772007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:46:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:52:12
User entered '2'	System	22 Oct 2020 16:19:42

US3772007

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:46:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:52:12
User entered '1'	System	22 Oct 2020 16:19:42

**US3772007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:46:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 09:52:12
User entered '804 (804)'	System	22 Oct 2020 16:19:42

US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:46:07

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:51:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN NICOTINE DEPENDENCE, PRODUCT: VARENICLINE TARTRATE, PRODUCTSYNONYM: CHANTIX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Mar 2021 23:53:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 23:53:49
Data point term sent to Coder	System	12 Mar 2021 23:52:19
User entered 'Chantix'	Emily Crews (b) (4) (b) (4)	12 Mar 2021 23:51:56



US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:46:07

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:51:16
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Mar 2021 23:51:56

US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:46:07

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:51:16
User entered 'Smoking Cessation'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Mar 2021 23:51:56

US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:46:07

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:51:16
User entered '1'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Mar 2021 23:51:56

US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:46:07

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:51:16
User entered 'mg (mg)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Mar 2021 23:51:56

US3772007

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:46:07**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:51:16
	(b) (4)	
User entered empty.	Emily Crews (b) (4)	12 Mar 2021 23:51:56
	(b) (4)	

**US3772007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:46:07**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:51:16
User entered 'twice daily (BID)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Mar 2021 23:51:56

US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:46:07

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:51:16
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	12 Mar 2021 23:51:56

US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:46:07

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:51:16
User entered 'Oral (ORAL)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Mar 2021 23:51:56



US3772007

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:46:07**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:51:16
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	12 Mar 2021 23:51:56

US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:46:07

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:51:16
User entered '25 Feb 2021'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Mar 2021 23:51:56

**US3772007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:46:07**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:51:16
User entered '0'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Mar 2021 23:51:56

**US3772007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:46:07**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:51:16
User entered 'Yes (Y)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Mar 2021 23:51:56

US3772007

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:46:07

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:51:16
User entered empty.	(b) (4) Emily Crews (b) (4) (b) (4)	12 Mar 2021 23:51:56

US3772007

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:46:07**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:51:16
User entered 'No (N)'	(b) (4) Emily Crews (b) (4) (b) (4)	12 Mar 2021 23:51:56

**US3772007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:46:07**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Mar 2021 23:51:56

**US3772007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:46:07**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Mar 2021 23:51:56



**US3772007**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:46:07**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Mar 2021 23:51:56

US3772007

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:46:07

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User closed query '24Oct2020(b) (6)': Please respond to query per eCRF guidelines. Thank you' (Site from CRA).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 03:37:27
Query '24Oct2020(b) (6)': Please respond to query per eCRF guidelines. Thank you' answered with 'Updated' (Site from CRA).	Emily Crews (b) (4) (b) (4)	26 Oct 2020 15:25:01
User entered 'No (N)'	Emily Crews (b) (4) (b) (4)	26 Oct 2020 15:24:53
User opened query '24Oct2020(b) (6)': Please respond to query per eCRF guidelines. Thank you' (Site from CRA).	(b) (4), (b) (6)	25 Oct 2020 03:35:40

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'USA-US107-2021-MRNA-1273-P301000009'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'Yes (Y)'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'No (N)'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'Yes (Y)'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'No (N)'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'No (N)'	System	16 Feb 2021 16:29:17



**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'No (N)'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'No (N)'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'Jamshid'	System	16 Feb 2021 16:29:17

US3772007

Folder: SAE USA-US107-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'Saleh'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered '3652 Eureka Way'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'Redding'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered '96001'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 16:22:13
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'US'	(b) (4) System	16 Feb 2021 16:30:05



US3772007

Folder: SAE USA-US107-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	16 Apr 2021 15:55:27
User entered '3'	System	30 Mar 2021 20:13:01
User entered '2'	System	15 Mar 2021 16:22:24
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
	(b) (4)	
User entered '1'	System	16 Feb 2021 16:30:05

US3772007

Folder: SAE USA-US107-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:07

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'USA-US107-2021-MRNA-1273-P301000009'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'Yes (Y)'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'No (N)'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'Yes (Y)'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'No (N)'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'No (N)'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'No (N)'	System	16 Feb 2021 16:29:17



**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'No (N)'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'Jamshid'	System	16 Feb 2021 16:29:17

US3772007

Folder: SAE USA-US107-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'Saleh'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered '3652 Eureka Way'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'Redding'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered '96001'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 16:22:13
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'US'	(b) (4) System	16 Feb 2021 16:30:05

US3772007

Folder: SAE USA-US107-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	16 Apr 2021 15:55:27
User entered '3'	System	30 Mar 2021 20:13:01
User entered '2'	System	15 Mar 2021 16:22:24
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
	(b) (4)	
User entered '1'	System	16 Feb 2021 16:30:05



**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:46:07**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered '16/Feb/2021 16:30'	(b) (4) System	16 Feb 2021 16:30:05

US3772007

Folder: SAE USA-US107-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:46:07

**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)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 16:22:13
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'I'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:30:05

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'USA-US107-2021-MRNA-1273-P301000009'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'Yes (Y)'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'No (N)'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'Yes (Y)'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'No (N)'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'No (N)'	System	16 Feb 2021 16:29:17



**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'No (N)'	System	16 Feb 2021 16:29:17

US3772007

Folder: SAE USA-US107-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:07

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'No (N)'	System	16 Feb 2021 16:29:17

US3772007

Folder: SAE USA-US107-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'Jamshid'	System	16 Feb 2021 16:29:17

US3772007

Folder: SAE USA-US107-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'Saleh'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered '3652 Eureka Way'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'Redding'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered '96001'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 16:22:13
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'US'	(b) (4) System	16 Feb 2021 16:30:05



US3772007

Folder: SAE USA-US107-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	16 Apr 2021 15:55:27
User entered '3'	System	30 Mar 2021 20:13:01
User entered '2'	System	15 Mar 2021 16:22:24
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
	(b) (4)	
User entered '1'	System	16 Feb 2021 16:30:05

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:46:07**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:11
User entered '15/Mar/2021 11:22'	(b) (4) System	15 Mar 2021 16:22:24

US3772007

Folder: SAE USA-US107-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:46:07

**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)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 20:12:50
User signature succeeded.	Jamshid Saleh (b) (4)	23 Mar 2021 02:48:11
User entered 'I'	(b) (4) (b) (4), (b) (6)	15 Mar 2021 16:22:24

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'USA-US107-2021-MRNA-1273-P301000009'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'Yes (Y)'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'No (N)'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'Yes (Y)'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'No (N)'	System	16 Feb 2021 16:29:17



**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'No (N)'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'No (N)'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'No (N)'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'Jamshid'	System	16 Feb 2021 16:29:17

US3772007

Folder: SAE USA-US107-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'Saleh'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered '3652 Eureka Way'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'Redding'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered '96001'	System	16 Feb 2021 16:29:17



US3772007

Folder: SAE USA-US107-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:07

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 16:22:13
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'US'	(b) (4) System	16 Feb 2021 16:30:05

US3772007

Folder: SAE USA-US107-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	16 Apr 2021 15:55:27
User entered '3'	System	30 Mar 2021 20:13:01
User entered '2'	System	15 Mar 2021 16:22:24
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
	(b) (4)	
User entered '1'	System	16 Feb 2021 16:30:05

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 09:46:07**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	31 Mar 2021 19:29:24
User entered '30/Mar/2021 15:12'	(b) (4) System	30 Mar 2021 20:13:01

US3772007

Folder: SAE USA-US107-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:46:07

**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)	16 Apr 2021 15:55:33
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	31 Mar 2021 19:29:24
User entered 'I'	(b) (4), (b) (6)	30 Mar 2021 20:13:01

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'USA-US107-2021-MRNA-1273-P301000009'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'Yes (Y)'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'No (N)'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'Yes (Y)'	System	16 Feb 2021 16:29:17



**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'No (N)'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'No (N)'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'No (N)'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'No (N)'	System	16 Feb 2021 16:29:17

US3772007

Folder: SAE USA-US107-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:07

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'Jamshid'	System	16 Feb 2021 16:29:17

US3772007

Folder: SAE USA-US107-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:07

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'Saleh'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered '3652 Eureka Way'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered 'Redding'	System	16 Feb 2021 16:29:17



**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:29:45
User entered '96001'	System	16 Feb 2021 16:29:17

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:46:07**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 00:07:50
Reviewed for Safety.	(b) (4), (b) (6)	15 Mar 2021 16:22:13
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
User entered 'US'	(b) (4) System	16 Feb 2021 16:30:05

US3772007

Folder: SAE USA-US107-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:46:07

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	16 Apr 2021 15:55:27
User entered '3'	System	30 Mar 2021 20:13:01
User entered '2'	System	15 Mar 2021 16:22:24
User signature succeeded.	Jamshid Saleh (b) (4)	16 Feb 2021 20:33:59
	(b) (4)	
User entered '1'	System	16 Feb 2021 16:30:05

**US3772007**

**Folder: SAE USA-US107-2021-MRNA-1273-P301000009**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 09:46:07**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:44:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:44:38
User entered '16/Apr/2021 11:55'	(b) (4) System	16 Apr 2021 15:55:27

US3772007

Folder: SAE USA-US107-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:46:07

**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)
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:44:21
User signature succeeded.	Jamshid Saleh (b) (4)	23 Apr 2021 22:44:38
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:55:33
User entered 'I'		16 Apr 2021 15:55:27