

US3892042 (Prod: Synexus Clinical Research US, Inc. - Salt Lake City)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:22:50

All time stamps listed in this document are displayed in GMT

US3892042

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 18:29:00

Generated On: 10 Jun 2021 10:22:50

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Participant ID

US3892042

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

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US3892042

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3892042

Folder: Screening

Form: Demographics

Data signed: (b) (4) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

Date of Birth (MMM yyyy)	(b) (6) 1976
Age	44
Age Units	YEARS
Age (Derived)	44
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

Date of Informed Consent ( <i>dd MMM yyyy</i> )	01 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

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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) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

Were any significant conditions reported?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 29 Mar 2021 17:51:34

Generated On: 10 Jun 2021 10:22:50

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



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 29 Mar 2021 17:51:34

Generated On: 10 Jun 2021 10:22:50

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3892042

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 29 Mar 2021 17:51:34

Generated On: 10 Jun 2021 10:22:50

Condition	INGUINAL HERNIA
Start date (dd MMM yyyy)	UN UNK 2018
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 JUN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JUN 2020
Stop Year (derived)	2020

US3892042

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 29 Mar 2021 17:51:34

Generated On: 10 Jun 2021 10:22:50

Condition	HISTORY OF BOTOX FOR COSMETIC PURPOSES
Start date (dd MMM yyyy)	UN JAN 2020
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 JAN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JAN 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	01 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	11:00 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 11:00
Height ( <i>xxx.x</i> )	201.0 cm
Weight ( <i>xxx.x</i> )	92.4 kg
BMI ( <i>xxx.x</i> )	22.87072 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) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 18:29:25

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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) 23 Feb 2021 18:29:25

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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) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 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	VISIT1



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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

What was the date of randomization? (dd MMM yyyy) 01 SEP 2020

What was the participant's randomization number? 110350

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

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) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

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)	01 SEP 2020
Time of assessment (00:00-23:59)	11:00 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 11:00
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

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)	01 SEP 2020
Time of assessment (00:00-23:59)	13:27 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 13:27
Temperature (xxx.x)	97.0 F
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)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

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) 01 SEP 2020

What was the treatment time? (00:00-23:59) 12:53 (24 HR)

Treatment Date and Time (derived) 01 SEP 2020 12:53

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) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	01 SEP 2020
Collection time (00:00-23:59)	12:28 (24 HR)
Collection date and time (derived)	01 SEP 2020 12:28

US3892042

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

Collection date (dd MMM yyyy)			01 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:25	01 SEP 2020 12:25
Nasopharyngeal Swab 2	No		



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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 13:28

PC Open Date & Time

01 SEP 2020 13:13

PC Close Date & Time

01 SEP 2020 15:43

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.1 °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	02 SEP 2020 07:14
PC Open Date & Time	01 SEP 2020 16:38
PC Close Date & Time	02 SEP 2020 11:59

US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

02 SEP 2020 18:31

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

03 SEP 2020 13:00

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

04 SEP 2020 12:35

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

05 SEP 2020 13:00

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:22:50

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59



US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

07 SEP 2020 22:27

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 13:28

PC Open Date & Time

01 SEP 2020 13:13

PC Close Date & Time

01 SEP 2020 15:43

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:22:50

**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

02 SEP 2020 07:13

PC Open Date & Time

01 SEP 2020 16:38

PC Close Date & Time

02 SEP 2020 11:59

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

80

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

03 SEP 2020 07:09

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:22:50

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

80

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

03 SEP 2020 13:00

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:22:50

**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

04 SEP 2020 12:35

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:22:50

**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

05 SEP 2020 13:00

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59



US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:22:50

**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

07 SEP 2020 22:27

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:22:50

**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 ☐

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:22:50

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 13:29
PC Open Date & Time	01 SEP 2020 13:13
PC Close Date & Time	01 SEP 2020 15:43

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:22:50

**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 ☐

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:22:50

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 07:14
PC Open Date & Time	01 SEP 2020 16:38
PC Close Date & Time	02 SEP 2020 11:59

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:22:50

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:22:50

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 07:11
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:22:50

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 ☒



US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:22:50

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 13:00
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:22:50

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 12:35
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:22:50

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 13:01
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:22:50

**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)

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US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:22:50

Yes ☐

PC Time stamp

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:22:50

**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

55 of 2573

EAB) (1725)



US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:22:50

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 22:28
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3892042

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3892042

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892042

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3892042

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892042

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

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*

US3892042

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892042

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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



US3892042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

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)	28 SEP 2020
Time of assessment (00:00-23:59)	07:10 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 07:10
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3892042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

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)	28 SEP 2020
Time of assessment (00:00-23:59)	08:47 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 08:47
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3892042

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

US3892042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

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) 28 SEP 2020

What was the treatment time? (00:00-23:59) 08:14 (24 HR)

Treatment Date and Time (derived) 28 SEP 2020 08:14

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

US3892042

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 SEP 2020

Collection time (00:00-23:59)

07:23 (24 HR)

Collection date and time (derived)

28 SEP 2020 07:23

US3892042

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

Collection date (dd MMM yyyy)			28 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	07:28	28 SEP 2020 07:28
Nasopharyngeal Swab 2	No		

US3892042

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

97.1 °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 28 SEP 2020 08:49

PC Open Date & Time 28 SEP 2020 08:34

PC Close Date & Time 28 SEP 2020 11:04



US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:22:50

**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

98.4 °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	29 SEP 2020 03:29
PC Open Date & Time	28 SEP 2020 11:59
PC Close Date & Time	29 SEP 2020 11:59

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	99.0 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	29 SEP 2020 15:24
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:22:50

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.7 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	30 SEP 2020 16:18
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:22:50

**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

01 OCT 2020 12:33

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:22:50

**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

96.8 °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

03 OCT 2020 06:35

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

03 OCT 2020 22:41

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 12:19

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 08:49

PC Open Date & Time

28 SEP 2020 08:34

PC Close Date & Time

28 SEP 2020 11:04



US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:22:50

**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

29 SEP 2020 03:30

PC Open Date & Time

28 SEP 2020 11:59

PC Close Date & Time

29 SEP 2020 11:59

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

65

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

29 SEP 2020 15:26

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:22:50

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

50

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

30 SEP 2020 16:18

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:22:50

**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

01 OCT 2020 12:33

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:22:50

**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

03 OCT 2020 06:36

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:22:50

**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

03 OCT 2020 22:42

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:22:50

**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

04 OCT 2020 12:20

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:22:50

**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 ☐



US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:22:50

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

No ☒

Yes ☐

PC Time stamp	28 SEP 2020 08:49
PC Open Date & Time	28 SEP 2020 08:34
PC Close Date & Time	28 SEP 2020 11:04

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:22:50

**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 ☐

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:22:50

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 03:31
PC Open Date & Time	28 SEP 2020 11:59
PC Close Date & Time	29 SEP 2020 11:59

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:22:50

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:22:50

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 15:27
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:22:50

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 ☒

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:22:50

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 16:18
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:22:50

**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 ☒



US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:22:50

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 12:34
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:22:50

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:22:50

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 06:36
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:22:50

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 ☒

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:22:50

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 22:42
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:22:50

**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

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Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:22:50

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 12:20
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3892042

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3892042

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892042

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3892042

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892042

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3892042

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892042

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 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

US3892042

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	27 OCT 2020
Time of assessment (00:00-23:59)	07:12 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 07:12
Temperature (xxx.x)	97.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3892042

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 OCT 2020

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



US3892042

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 OCT 2020
Collection time (00:00-23:59)	07:24 (24 HR)
Collection date and time (derived)	27 OCT 2020 07:24

US3892042

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

<b>TIMEPOINT</b>	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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 NOV 2020 12:34:49
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3892042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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

09 NOV 2020 09:14:18

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3892042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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

16 NOV 2020 12:01:45

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	21 NOV 2020 22:51:01
Patient Cloud Open Date & Time	19 NOV 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
117 of 2573	

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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[Patient Cloud Close Date & Time](#)

23 NOV 2020 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 NOV 2020 09:57:58
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59



US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 DEC 2020 05:24:28
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 DEC 2020 06:33:16

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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

17 DEC 2020 08:37:55

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 16:21:59

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

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	31 DEC 2020 00:22:33
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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

11 JAN 2021 08:34:11

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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

18 JAN 2021 14:13:13

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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

21 JAN 2021 14:57:32

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59



US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 JAN 2021 04:32:16

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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

04 FEB 2021 17:57:30

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 FEB 2021 00:51:09

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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 FEB 2021 07:47:57

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	26 FEB 2021 07:30:23
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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

04 MAR 2021 00:47:28

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

<b>TIMEPOINT</b>	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 MAR 2021 11:24:04
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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

18 MAR 2021 09:46:44

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59



US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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

29 MAR 2021 07:43:58

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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

05 APR 2021 09:58:01

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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

09 APR 2021 10:54:26

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

<b>TIMEPOINT</b>	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 APR 2021 14:06:41
Patient Cloud Open Date & Time	15 APR 2021 00:01
Patient Cloud Close Date & Time	19 APR 2021 23:59

US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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

22 APR 2021 00:01:33

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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

29 APR 2021 00:07:03

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

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

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

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24 MAY 2021 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

DAY 271

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Open Date & Time](#)

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27 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAY 2021 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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 ☐

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

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

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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°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 ☐

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

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

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

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28 JUN 2021 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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 ☐

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Open Date & Time](#)

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01 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 JUL 2021 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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 ☐

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Open Date & Time](#)

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08 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 JUL 2021 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Open Date & Time](#)

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15 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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19 JUL 2021 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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

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

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

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26 JUL 2021 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

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

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Open Date & Time](#)

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29 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 AUG 2021 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

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"/>

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

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09 AUG 2021 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

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

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2021 23:59
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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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°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 ☐

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	19 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	23 AUG 2021 23:59
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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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 ☐

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	26 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	30 AUG 2021 23:59
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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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°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 ☐

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 SEP 2021 23:59

US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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 ☐

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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°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 ☐

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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



US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

TIMEPOINT	DAY 397
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Open Date & Time](#)

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30 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 OCT 2021 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

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

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

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11 OCT 2021 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

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

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

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18 OCT 2021 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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 ☐

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 OCT 2021 23:59



US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Open Date & Time](#)

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28 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 NOV 2021 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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 ☐

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Open Date & Time](#)

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04 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 NOV 2021 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

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

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

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

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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 ☐

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Open Date & Time](#)

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25 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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29 NOV 2021 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

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"/>

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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°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 ☐

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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 ☐

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Open Date & Time](#)

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16 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 DEC 2021 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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 ☐

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

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

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

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

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

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10 JAN 2022 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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 ☐

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

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17 JAN 2022 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

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24 JAN 2022 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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 ☐

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

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31 JAN 2022 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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 ☐

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

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

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Open Date & Time](#)

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10 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 FEB 2022 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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 ☐

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

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21 FEB 2022 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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 ☐

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

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28 FEB 2022 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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 ☐

**US3892042**

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

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**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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 ☐

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Open Date & Time](#)

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10 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 MAR 2022 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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 ☐

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

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21 MAR 2022 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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 ☐

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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28 MAR 2022 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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 ☐

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

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04 APR 2022 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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 ☐

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

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11 APR 2022 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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 ☐

**US3892042**

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

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**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

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18 APR 2022 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

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"/>

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Open Date & Time](#)

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21 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 APR 2022 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

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

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

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"/>

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

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

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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12 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAY 2022 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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 ☐

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

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

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

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30 MAY 2022 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

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

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Open Date & Time](#)

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02 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 JUN 2022 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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 ☐

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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°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 ☐

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Open Date & Time](#)

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16 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 JUN 2022 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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 ☐

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

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27 JUN 2022 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59



US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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 ☐

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	07 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 JUL 2022 23:59

US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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 ☐

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

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18 JUL 2022 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

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"/>

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

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01 AUG 2022 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

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08 AUG 2022 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

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

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

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15 AUG 2022 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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 ☐

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

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22 AUG 2022 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

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

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 AUG 2022 23:59
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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

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

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

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"/>

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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°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 ☐

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 SEP 2022 23:59

US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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 ☐

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

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26 SEP 2022 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°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"/>

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

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10 OCT 2022 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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 ☐

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 OCT 2022 23:59

US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**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 ☐

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	20 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 OCT 2022 23:59
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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

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31 OCT 2022 23:59

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US3892042

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

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"/>

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

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[Patient Cloud Close Date & Time](#)

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07 NOV 2022 23:59

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US3892042

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:22:50

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
Yes	No	01 MAR 2021 08:17:47

US3892042

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

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

SUBJECT WAS IN  
CONVALESCENT PERIOD -  
ILLNESS VISIT

*If Contact Not Made, please provide Comments*

US3892042

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:29:25

Generated On: 10 Jun 2021 10:22:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892042

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3892042

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892042

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3892042

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892042

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3892042

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892042

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 16:26:21

Generated On: 10 Jun 2021 10:22:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 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

US3892042

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 16:26:21

Generated On: 10 Jun 2021 10:22:50

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) \_\_\_\_\_

US3892042

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 16:26:21

Generated On: 10 Jun 2021 10:22:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 MAR 2021

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



US3892042

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 16:26:21

Generated On: 10 Jun 2021 10:22:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 MAR 2021
Collection time (00:00-23:59)	07:32 (24 HR)
Collection date and time (derived)	30 MAR 2021 07:32

US3892042

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 16:26:21

Generated On: 10 Jun 2021 10:22:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3892042

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3892042

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3892042**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:22:50**

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*

**US3892042**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:22:50**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3892042

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

Date of Contact 19 NOV 2020

Time of Contact

Date and Time of Contact (derived)

Type of Contact

Clinic Visit - Scheduled ☐

Clinical Visit - Unscheduled ☐

Safety Call ☒

Convalescent Tele-visit ☐

Has the subject reported symptoms of SARS-COV-2?

Yes ☒

No ☐

US3892042

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

Symptom Day

Day 1	<input checked="" type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



US3892042

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	18 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3892042

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

321 of 2573

US3892042

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3892042

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3892042

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



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Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	20 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	95 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	95.8 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	21 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	95.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



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Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 NOV 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	96.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	23 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	95.8 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input checked="" type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3892042

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



US3892042

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	96.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3892042

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

Date of Visit	20 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	20 NOV 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3892042

Folder: Covid-19 Assessment 19 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	22 NOV 2020
Day 5	Yes	24 NOV 2020
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3892042

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3892042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 NOV 2020
Time of assessment (00:00-23:59)	09:00 (24 HR)
Vital Signs Date and Time (derived)	20 NOV 2020 09:00
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	95.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3892042

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 NOV 2020

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

US3892042

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

20 NOV 2020

US3892042

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

Was this visit performed? Yes ☐  
No ☒

Visit date (dd MMM yyyy)

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

Folder OID SICKD28

US3892042

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

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) \_\_\_\_\_

US3892042

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

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.*

US3892042

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☐

No ☐

NA (COVID-19 Negative) ☒

Date of Collection

US3892042

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

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

Visit date (dd MMM yyyy)	26 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3892042

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 16:26:21

Generated On: 10 Jun 2021 10:22:50

Date of updated informed consent (*dd MMM yyyy*) 26 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (*dd MMM yyyy*) 21 DEC 2020

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

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



US3892042

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 JAN 2021
Collection time (00:00-23:59)	09:59 (24 HR)
Collection date and time (derived)	26 JAN 2021 09:59

US3892042

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 JAN 2021
Collection time (00:00 - 23:59)	10:08
Collection Date and Time (derived)	26 JAN 2021 10:08

US3892042

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 18:29:00

Generated On: 10 Jun 2021 10:22:50

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3892042

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Mar 2021 14:31:20

Generated On: 10 Jun 2021 10:22:50

AEID

Adverse event

UPPER RESPIRATORY TRACT  
INFECTION

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)

18 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

11 JAN 2021

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 ☐

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Mar 2021 14:31:20

Generated On: 10 Jun 2021 10:22:50

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

US3892042

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Mar 2021 14:31:20

Generated On: 10 Jun 2021 10:22:50

AEID	USA-US209-2021-MRNA-1273-P30 1000003
Adverse event	SPINAL FRACTURE ON T11 AND T12
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)	20 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	23 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	20 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	23 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Mar 2021 14:31:20

Generated On: 10 Jun 2021 10:22:50

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	PAIN, PHYSICAL IMPAIRMENT AND SURGICAL CHANGES
Narrative	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Mar 2021 14:31:20

Generated On: 10 Jun 2021 10:22:50

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SUBJECT CONTACTED FOR  
DAY 179 SAFETY PHONE CALL  
AND STATED HE IS  
CURRENTLY HOSPITALIZED.  
SUBJECT WENT SLEDDING ON  
20FEB2021 AND CRASHED,  
RESULTING IN FRACTURING  
HIS SPINE AT T11 AND T12.  
SUBJECT UNDERWENT  
SURGERY FOR SPINAL FUSION  
22FEB2021. POTENTIAL  
DISCHARGE FOR TOMORROW.  
WILL CONTACT SUBJECT ON  
WEDNESDAY TO FOLLOW UP.

SUBJECT SUFFERED A SPINAL  
FRACTURE ON 20 FEB. 2021,  
AND HAD SURGERY ON 22 FEB.  
2021. SAE IS CLOSED WITH  
SEQUELAE OF PAIN, PHYSICAL  
IMPAIRMENT AND SURGICAL  
CHANGES AS OF DATE OF  
DISCHARGE 23 FEB. 2021.  
POST-SURGICAL PAIN IS  
OPENED AS SEPARATE AE.

SARS-COV-2 BY PCR:  
NEGATIVE. COLLECTED ON 20  
FEB. 2021 @ 15:14 MST.

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Mar 2021 14:31:20

Generated On: 10 Jun 2021 10:22:50

AEID	
Adverse event	POST-SURGICAL PAIN
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)	22 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 checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Mar 2021 14:31:20

Generated On: 10 Jun 2021 10:22:50

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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	PAIN FOLLOW SURGERY DID NOT PROLONG HOSPITALIZATION AND IT IS NOT AN SAE. SURGERY DATE COLLECTED BASED ON MEDICAL RECORDS.
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
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**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Data signed:** (b) (4) 23 Mar 2021 14:31:20

**Generated On: 10 Jun 2021 10:22:50**

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Admitted to ICU Derived (CSA Programming Field Only)

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US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 18:29:00

Generated On: 10 Jun 2021 10:22:50

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

Yes ☒

No ☐

---

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

---

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication HEADACHES

Dose per administration 800

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) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

Name of Medication ZYTREC

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

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



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication PROPHYLAXIS FOR INFLUENZA

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

Name of Medication NASAL STEROID

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" 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)	15 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication PAIN AT THE INJECTION SITE  
AND FEVER

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 22:40:20

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	29 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

Name of Medication FLEXERIL

Prophylaxis Yes ☐  
No ☒

Indication SPINAL FRACTURE

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication SPINAL FRACTURE

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	21 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

Name of Medication OXYCODONE

Prophylaxis Yes ☐  
No ☒

Indication SPINAL FRACTURE

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

Name of Medication TORADOL

Prophylaxis Yes ☐  
No ☒

Indication SPINAL FRACTURE

Dose per administration 15

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 (9)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	21 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	22 FEB 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

Name of Medication MORPHINE

Prophylaxis Yes ☐  
No ☒

Indication SPINAL FRACTURE

Dose per administration 8

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		20 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		20 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

Name of Medication VALIUM

Prophylaxis Yes ☐  
No ☒

Indication SPINAL FRACTURE

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)		20 FEB 2021
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

Name of Medication DILAUDID

Prophylaxis Yes ☐  
No ☒

Indication SPINAL FRACTURE

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy) 20 FEB 2021		
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

Name of Medication BOTOX

Prophylaxis Yes ☐  
No ☒

Indication ELECTIVE COSMETIC  
PROCEDURE

Dose per administration 66

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

Name of Medication BOTOX

Prophylaxis Yes ☐  
No ☒

Indication ELECTIVE COSMETIC  
PROCEDURE

Dose per administration 66

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

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



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

Name of Medication FLEXERIL

Prophylaxis Yes ☐  
No ☒

Indication POST SURGICAL PAIN

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		21 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication POST SURGICAL PAIN

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	21 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	18 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

Name of Medication POLYETHYLENE GLYCOL

Prophylaxis Yes ☒  
No ☐

Indication BOWEL PROPHYLAXIS

Dose per administration 17

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 (17)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

	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)		20 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

Name of Medication VERSED

Prophylaxis Yes ☐  
No ☒

Indication SPINAL FRACTURE

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		20 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		20 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

Name of Medication HYDROMORPHONE

Prophylaxis Yes ☐  
No ☒

Indication SPINAL FRACTURE

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		20 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		20 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

Name of Medication ENDOTRACHEAL ANESTHESIA

Prophylaxis Yes ☐  
No ☒

Indication SPINAL FRACTURE

Dose per administration 1

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

If dose unit is Other, specify DOSE

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 (20)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

	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 checked="" 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)		22 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 22 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

Name of Medication VANCOMYCIN POWDER

Prophylaxis Yes ☐  
No ☒

Indication SPINAL FRACTURE

Dose per administration 1

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

If dose unit is Other, specify DOSE

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 (21)

Data signed: (b) (4) 26 Apr 2021 22:40:20

Generated On: 10 Jun 2021 10:22:50

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify		INTRA-OPERATIVE
Start date (dd MMM yyyy)	22 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		22 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Feb 2021 18:29:01

Generated On: 10 Jun 2021 10:22:50

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 12 Apr 2021 16:26:21

Generated On: 10 Jun 2021 10:22:50

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
22 FEB 2021	SPINAL FUSION	Adverse Event	
20 FEB 2021	CERVICAL, THORACIC, AND LUMBAR X-RAY	Diagnostic	
20 FEB 2021	LUMBAR CT SCAN (WITHOUT CONTRAST)	Diagnostic	
20 FEB 2021	CHEST X-RAY	Diagnostic	



US3892042

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:22:50

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

US3892042

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:22:50

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 ☐

US3892042

Folder: SAE USA-US209-2021-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 12 Apr 2021 16:26:21

Generated On: 10 Jun 2021 10:22:50

SAEID	USA-US209-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	ADAMS
Site Address: Street	5251 S GREEN ST
Site Address: City	MURRAY
Site Address: State	UT
Site Address: Postal Code	84123
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3892042

Folder: SAE USA-US209-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 12 Apr 2021 16:26:21

Generated On: 10 Jun 2021 10:22:50

SAEID	USA-US209-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	ADAMS
Site Address: Street	5251 S GREEN ST
Site Address: City	MURRAY
Site Address: State	UT
Site Address: Postal Code	84123
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	23/FEB/2021 15:48
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

US3892042

Folder: SAE USA-US209-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 12 Apr 2021 16:26:21

Generated On: 10 Jun 2021 10:22:50

SAEID	USA-US209-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	ADAMS
Site Address: Street	5251 S GREEN ST
Site Address: City	MURRAY
Site Address: State	UT
Site Address: Postal Code	84123
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	25/FEB/2021 11:34
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

US3892042

Folder: SAE USA-US209-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 12 Apr 2021 16:26:21

Generated On: 10 Jun 2021 10:22:50

SAEID	USA-US209-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	ADAMS
Site Address: Street	5251 S GREEN ST
Site Address: City	MURRAY
Site Address: State	UT
Site Address: Postal Code	84123
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	02/MAR/2021 11:02
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

US3892042

Folder: SAE USA-US209-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 12 Apr 2021 16:26:21

Generated On: 10 Jun 2021 10:22:50

SAEID	USA-US209-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	ADAMS
Site Address: Street	5251 S GREEN ST
Site Address: City	MURRAY
Site Address: State	UT
Site Address: Postal Code	84123
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	03/MAR/2021 09:32
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

US3892042

Folder: SAE USA-US209-2021-MRNA-1273-P301000003

Form: Safety Report Form (5)

Data signed: (b) (4) 12 Apr 2021 16:26:21

Generated On: 10 Jun 2021 10:22:50

SAEID	USA-US209-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	ADAMS
Site Address: Street	5251 S GREEN ST
Site Address: City	MURRAY
Site Address: State	UT
Site Address: Postal Code	84123
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	10/MAR/2021 09:08
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



US3892042

Folder: SAE USA-US209-2021-MRNA-1273-P301000003

Form: Safety Report Form (6)

Data signed: (b) (4) 12 Apr 2021 16:26:21

Generated On: 10 Jun 2021 10:22:50

SAEID	USA-US209-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	ADAMS
Site Address: Street	5251 S GREEN ST
Site Address: City	MURRAY
Site Address: State	UT
Site Address: Postal Code	84123
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	11/MAR/2021 07:48
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

US3892042

Folder: SAE USA-US209-2021-MRNA-1273-P301000003

Form: Safety Report Form (7)

Data signed: (b) (4) 12 Apr 2021 16:26:21

Generated On: 10 Jun 2021 10:22:50

SAEID	USA-US209-2021-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MICHAEL
Investigator's Last Name	ADAMS
Site Address: Street	5251 S GREEN ST
Site Address: City	MURRAY
Site Address: State	UT
Site Address: Postal Code	84123
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	19/MAR/2021 09:51
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

US3892042 (Prod: Synexus Clinical Research US, Inc. - Salt Lake City)

**US3892042**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 10:22:50**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'US3892042'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 16:44:35

**US3892042**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:22:50**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:57:03

**US3892042**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered '01 SEP 2020'	RWS_ENDPOINT	01 Sep 2020 16:44:36
	ENDPOINT (b) (4)	

US3892042

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	01 Sep 2020 18:57:03

**US3892042**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:22:50**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User entered 'SCRN'	System	01 Sep 2020 18:57:03



US3892042

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:22:50

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered (b) (6) 1976'	RWS_ENDPOINT	01 Sep 2020 16:44:38
	ENDPOINT (b) (4)	

**US3892042**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:22:50**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered '44'	(b) (4), (b) (6)	01 Sep 2020 17:27:49

**US3892042**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:22:50**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User entered 'YEARS'	System	01 Sep 2020 17:27:49

**US3892042**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:22:50**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User entered '44'	System	01 Sep 2020 17:28:06

**US3892042**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:22:50**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered 'Male (M)'	(b) (4), (b) (6)	01 Sep 2020 17:27:49

**US3892042**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:22:50**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	01 Sep 2020 17:27:49

**US3892042**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:22:50**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	01 Sep 2020 17:27:49

**US3892042**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:22:50**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:27:49



**US3892042**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:22:50**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:27:49

**US3892042**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:22:50**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:27:49

**US3892042**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:22:50**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:27:49

**US3892042**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:22:50**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:27:49

US3892042

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:22:50

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:27:49

**US3892042**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:22:50**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:27:49

**US3892042**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:22:50**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	01 Sep 2020 17:27:49

US3892042

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:22:50

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered '01 Sep 2020'	(b) (4), (b) (6)	01 Sep 2020 17:28:06



**US3892042**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User entered 'Sep 2020'	System	01 Sep 2020 17:28:06

**US3892042**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User entered '2020'	System	01 Sep 2020 17:28:06

**US3892042**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 10:22:50**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	01 Sep 2020 17:28:06

US3892042

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 17:28:06

**US3892042**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 10:22:50**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:28:06

**US3892042**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 10:22:50**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	01 Sep 2020 17:28:06

US3892042

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:22:50

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	01 Sep 2020 17:28:06

US3892042

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:22:50

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered empty.	RWS_ENDPOINT	01 Sep 2020 16:44:36
	ENDPOINT (b) (4)	



**US3892042**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 10:22:50**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User entered '1'	System	01 Sep 2020 18:57:21

US3892042

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Sep 2020 18:57:21

**US3892042**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 10 Jun 2021 10:22:50**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	01 Sep 2020 21:58:00
	(b) (4)	

US3892042

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:22:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 21:59:32
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 21:59:32
	(b) (4)	
Data point term sent to Coder System		01 Sep 2020 21:58:50
User entered 'HEADACHES'	Andryelle Toledo (b) (4)	01 Sep 2020 21:58:25
	(b) (4)	

**US3892042**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered 'UN UNK 2000'	Andryelle Toledo (b) (4)	01 Sep 2020 21:58:25
	(b) (4)	

**US3892042**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	01 Sep 2020 21:58:25
	(b) (4)	

**US3892042**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	01 Sep 2020 21:58:25
	(b) (4)	

**US3892042**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	01 Sep 2020 21:58:25
	(b) (4)	



**US3892042**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	01 Sep 2020 21:58:25
	(b) (4)	

**US3892042**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User entered 'Jan 2000'	System	01 Sep 2020 21:58:25

**US3892042**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User entered '2000'	System	01 Sep 2020 21:58:25

**US3892042**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User entered empty.	System	01 Sep 2020 21:58:25

**US3892042**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User entered empty.	System	01 Sep 2020 21:58:25

US3892042

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:22:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 22:13:41
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 22:13:41
	(b) (4)	
Data point term sent to Coder	System	01 Sep 2020 22:13:04
User entered 'SEASONAL ALLERGIES'	Andryelle Toledo (b) (4)	01 Sep 2020 22:12:28
	(b) (4)	

**US3892042**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered 'UN UNK 2012'	Andryelle Toledo (b) (4)	01 Sep 2020 22:12:28
	(b) (4)	

**US3892042**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	01 Sep 2020 22:12:28
	(b) (4)	



**US3892042**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	01 Sep 2020 22:12:28
	(b) (4)	

**US3892042**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	01 Sep 2020 22:12:28
	(b) (4)	

**US3892042**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	01 Sep 2020 22:12:28
	(b) (4)	

**US3892042**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User entered 'Jan 2012'	System	01 Sep 2020 22:12:28

**US3892042**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User entered '2012'	System	01 Sep 2020 22:12:28

**US3892042**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User entered empty.	System	01 Sep 2020 22:12:28

**US3892042**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User entered empty.	System	01 Sep 2020 22:12:28

US3892042

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:22:50

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Inguinal hernias, PT: Inguinal hernia, LLT: Inguinal hernia - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 22:13:41
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Sep 2020 22:13:41
	(b) (4)	
Data point term sent to Coder	System	01 Sep 2020 22:13:04
User entered 'INGUINAL HERNIA'	Andryelle Toledo (b) (4)	01 Sep 2020 22:12:56
	(b) (4)	



**US3892042**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered 'UN UNK 2018'	Andryelle Toledo (b) (4)	01 Sep 2020 22:12:56
	(b) (4)	

**US3892042**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	01 Sep 2020 22:12:56
	(b) (4)	

**US3892042**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	01 Sep 2020 22:12:56
	(b) (4)	

**US3892042**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered 'UN Jun 2020'	Andryelle Toledo (b) (4)	01 Sep 2020 22:12:56
	(b) (4)	

**US3892042**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	01 Sep 2020 22:12:56
	(b) (4)	

**US3892042**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User entered 'Jan 2018'	System	01 Sep 2020 22:12:56

**US3892042**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User entered '2018'	System	01 Sep 2020 22:12:56

**US3892042**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User entered 'Jun 2020'	System	01 Sep 2020 22:12:56



**US3892042**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User entered '2020'	System	01 Sep 2020 22:12:56

US3892042

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:22:50

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	29 Mar 2021 17:51:34
	(b) (4)	
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Botulinum toxin injection, LLT: Botulinum toxin injection - version MedDRA\\23.0.	Coder Import (b) (4)	19 Mar 2021 08:25:54
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Mar 2021 08:25:54
	(b) (4)	
Data point term sent to Coder	System	18 Mar 2021 20:53:35
User entered 'History of Botox for Cosmetic Purposes'	Leslie Iverson (b) (4)	18 Mar 2021 20:53:19
	(b) (4)	

**US3892042**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	29 Mar 2021 17:51:34
	(b) (4)	
User entered 'UN Jan 2020'	Leslie Iverson (b) (4)	18 Mar 2021 20:53:19
	(b) (4)	

**US3892042**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 10:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	29 Mar 2021 17:51:34
	(b) (4)	
User entered '0'	Leslie Iverson (b) (4)	18 Mar 2021 20:53:19
	(b) (4)	

US3892042

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:22:50

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	29 Mar 2021 17:51:34
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Mar 2021 20:53:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Mar 2021 20:53:29
User entered 'No (N)' reason for change: Data Entry Error	Leslie Iverson (b) (4)	18 Mar 2021 20:53:29
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Mar 2021 20:53:19
User entered empty.	Leslie Iverson (b) (4)	18 Mar 2021 20:53:19
	(b) (4)	

**US3892042**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	29 Mar 2021 17:51:34
	(b) (4)	
User entered 'UN Jan 2020'	Leslie Iverson (b) (4)	18 Mar 2021 20:53:19
	(b) (4)	

**US3892042**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 10:22:50**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	29 Mar 2021 17:51:34
	(b) (4)	
User entered '0'	Leslie Iverson (b) (4)	18 Mar 2021 20:53:19
	(b) (4)	

**US3892042**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User entered 'Jan 2020'	System	18 Mar 2021 20:53:19



**US3892042**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User entered '2020'	System	18 Mar 2021 20:53:19

**US3892042**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User entered 'Jan 2020'	System	18 Mar 2021 20:53:19

**US3892042**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User entered '2020'	System	18 Mar 2021 20:53:19

US3892042

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	01 Sep 2020 22:13:51
	(b) (4)	

US3892042

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered '01 Sep 2020'	Andryelle Toledo (b) (4)	01 Sep 2020 22:13:51
	(b) (4)	

US3892042

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered '11:00'	Andryelle Toledo (b) (4)	01 Sep 2020 22:13:51
	(b) (4)	

**US3892042**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User entered '01 Sep 2020 11:00'	System	01 Sep 2020 22:13:51

US3892042

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered '201.0' cm	Andryelle Toledo (b) (4)	01 Sep 2020 22:13:51
	(b) (4)	
DataPoint set to visible.	System	01 Sep 2020 18:57:21



US3892042

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:50

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered '92.4' kg	Andryelle Toledo (b) (4)	01 Sep 2020 22:13:51
	(b) (4)	
DataPoint set to visible.	System	01 Sep 2020 18:57:21

**US3892042**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User entered '22.87072'	System	01 Sep 2020 22:13:51
DataPoint set to visible.	System	01 Sep 2020 18:57:21

**US3892042**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User entered 'kg/m2'	System	01 Sep 2020 22:13:51
DataPoint set to visible.	System	01 Sep 2020 18:57:21

US3892042

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered missing code ND - Not Done.	Andryelle Toledo (b) (4)	01 Sep 2020 22:13:51
	(b) (4)	

US3892042

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:50

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	01 Sep 2020 22:13:51
	(b) (4)	

US3892042

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:50

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	01 Sep 2020 22:13:51
	(b) (4)	

**US3892042**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered missing code ND - Not Done.	Andryelle Toledo (b) (4)	01 Sep 2020 22:13:51
	(b) (4)	

**US3892042**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User entered 'bpm'	System	01 Sep 2020 22:13:51



US3892042

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered missing code ND - Not Done.	Andryelle Toledo (b) (4)	01 Sep 2020 22:13:51
	(b) (4)	

US3892042

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User entered 'breaths/min'	System	01 Sep 2020 22:13:51

US3892042

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered missing code ND - Not Done.	Andryelle Toledo (b) (4)	01 Sep 2020 22:13:51
	(b) (4)	

**US3892042**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User entered 'mmHg'	System	01 Sep 2020 22:13:51

US3892042

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered missing code ND - Not Done.	Andryelle Toledo (b) (4)	01 Sep 2020 22:13:51
	(b) (4)	

**US3892042**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User entered 'mmHg'	System	01 Sep 2020 22:13:51

**US3892042**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48

**US3892042**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48



US3892042

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:22:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	01 Sep 2020 22:14:11
	(b) (4)	

**US3892042**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 10:22:50**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered '01 Sep 2020'	Andryelle Toledo (b) (4)	01 Sep 2020 22:14:11
	(b) (4)	

US3892042

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	01 Sep 2020 22:14:46
	(b) (4)	

US3892042

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	01 Sep 2020 22:14:46
	(b) (4)	

US3892042

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	01 Sep 2020 22:14:46
	(b) (4)	

US3892042

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	01 Sep 2020 22:14:46
	(b) (4)	

US3892042

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	01 Sep 2020 22:14:46
	(b) (4)	

US3892042

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	01 Sep 2020 22:14:46
	(b) (4)	



US3892042

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	01 Sep 2020 22:14:46
	(b) (4)	

US3892042

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	01 Sep 2020 22:14:46
	(b) (4)	

US3892042

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	01 Sep 2020 22:14:46
	(b) (4)	

US3892042

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	01 Sep 2020 22:14:46
	(b) (4)	

US3892042

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	01 Sep 2020 22:14:46
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:50

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	01 Sep 2020 22:14:46
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:50

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	01 Sep 2020 22:14:46
	(b) (4)	

US3892042

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:50

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	01 Sep 2020 22:14:46
	(b) (4)	



US3892042

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:50

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	01 Sep 2020 22:14:46
	(b) (4)	

US3892042

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:50

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	01 Sep 2020 22:14:46
	(b) (4)	

US3892042

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:50

**Resides in high density housing** (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	01 Sep 2020 22:14:46
	(b) (4)	

US3892042

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:50

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	01 Sep 2020 22:14:46
	(b) (4)	

US3892042

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:50

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered 'I'	Andryelle Toledo (b) (4)	01 Sep 2020 22:14:46
	(b) (4)	

US3892042

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:50

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	01 Sep 2020 22:14:46
	(b) (4)	

US3892042

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:22:50

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	01 Sep 2020 22:14:46
	(b) (4)	

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:22:50**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:27:25



**US3892042**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '01 Sep 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:27:25

US3892042

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 17:27:25

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:22:50**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered 'VISIT1'	System	01 Sep 2020 17:27:25

US3892042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '01 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 18:24:32

US3892042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:22:50

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '110350'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 18:24:32

US3892042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:22:50

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 18:24:32

US3892042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:22:50

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)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:56:34

US3892042

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:22:50

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)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:56:34



**US3892042**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 10:22:50**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:56:34

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 10:22:50**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:56:34

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 10:22:50**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:56:34

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 10:22:50**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'No (N)'	Andryelle Toledo (b) (4)	30 Sep 2020 23:45:44
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:57:33
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:57:31

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 10:22:50**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered missing code ND - Not Done.	(b) (4) Andryelle Toledo (b) (4)	01 Sep 2020 22:16:16

US3892042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:22:50

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered missing code ND - Not Done.	(b) (4) Andryelle Toledo (b) (4)	01 Sep 2020 22:16:16

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 10:22:50**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered missing code ND - Not Done.	(b) (4) Andryelle Toledo (b) (4)	01 Sep 2020 22:16:16

US3892042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:22:50

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered missing code ND - Not Done.	(b) (4) Andryelle Toledo (b) (4)	01 Sep 2020 22:16:16



US3892042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User accepted default value 'Pre-Dose (PREDOSE)'	Andryelle Toledo (b) (4)	01 Sep 2020 22:16:16
	(b) (4)	

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	01 Sep 2020 22:16:16

US3892042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '01 Sep 2020'	(b) (4) Andryelle Toledo (b) (4)	01 Sep 2020 22:16:16

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '11:00'	(b) (4) Andryelle Toledo (b) (4)	01 Sep 2020 22:16:16

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered '01 Sep 2020 11:00'	System	01 Sep 2020 22:16:16

US3892042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '97.4' F	(b) (4) Andryelle Toledo (b) (4)	01 Sep 2020 22:16:16

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Oral (Oral)'	(b) (4) Andryelle Toledo (b) (4)	01 Sep 2020 22:16:16

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:22:50**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	01 Sep 2020 22:16:16



**US3892042**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '54'	(b) (4) Andryelle Toledo (b) (4)	01 Sep 2020 22:16:16

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered 'bpm'	System	01 Sep 2020 22:16:16

US3892042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '12'	(b) (4) Andryelle Toledo (b) (4)	01 Sep 2020 22:16:16

US3892042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered 'breaths/min'	System	01 Sep 2020 22:16:16

US3892042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:50

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '106'	(b) (4) Andryelle Toledo (b) (4)	01 Sep 2020 22:16:16

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered 'mmHg'	System	01 Sep 2020 22:16:16

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '69'	(b) (4) Andryelle Toledo (b) (4)	01 Sep 2020 22:16:16

US3892042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:50

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered 'mmHg'	System	01 Sep 2020 22:16:16



US3892042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:22:50

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered missing code ND - Not Done.	(b) (4) Andryelle Toledo (b) (4)	01 Sep 2020 22:16:16

US3892042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:22:50

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered missing code ND - Not Done.	(b) (4) Andryelle Toledo (b) (4)	01 Sep 2020 22:16:16

US3892042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User accepted default value 'Post-Dose (POSTDOSE)'	Andryelle Toledo (b) (4) (b) (4)	01 Sep 2020 22:16:16

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	01 Sep 2020 22:16:16

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:22:50**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '01 Sep 2020'	(b) (4) Andryelle Toledo (b) (4)	01 Sep 2020 22:16:16

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '13:27'	(b) (4) Andryelle Toledo (b) (4)	01 Sep 2020 22:16:16

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered '01 Sep 2020 13:27'	System	01 Sep 2020 22:16:16

US3892042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '97.0' F	(b) (4) Andryelle Toledo (b) (4)	01 Sep 2020 22:16:16



**US3892042**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Oral (Oral)'	(b) (4) Andryelle Toledo (b) (4)	01 Sep 2020 22:16:16

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:22:50**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	01 Sep 2020 22:16:16

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '55'	(b) (4) Andryelle Toledo (b) (4)	01 Sep 2020 22:16:16

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered 'bpm'	System	01 Sep 2020 22:16:16

US3892042

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '12'	(b) (4) Andryelle Toledo (b) (4)	01 Sep 2020 22:16:16

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered 'breaths/min'	System	01 Sep 2020 22:16:16

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '113'	(b) (4) Andryelle Toledo (b) (4)	01 Sep 2020 22:16:16

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered 'mmHg'	System	01 Sep 2020 22:16:16



**US3892042**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '76'	(b) (4) Andryelle Toledo (b) (4)	01 Sep 2020 22:16:16

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered 'mmHg'	System	01 Sep 2020 22:16:16

US3892042

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:22:50

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	01 Sep 2020 22:17:27
User entered 'Yes (Y)'	(b) (4)	
	Andryelle Toledo (b) (4)	01 Sep 2020 22:16:24
	(b) (4)	

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 10:22:50**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered empty; reason for change Data Entry Error	(b) (4)	01 Sep 2020 22:17:27
User entered '01 Sep 2020'	Andryelle Toledo (b) (4)	01 Sep 2020 22:16:24
	(b) (4)	

US3892042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:22:50

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:57:59

US3892042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:22:50

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:57:59

US3892042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:57:59

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:22:50**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 18:57:59



US3892042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:22:50

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '01 Sep 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:57:59

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:22:50**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '12:53'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:57:59

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:22:50**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered '01 Sep 2020 12:53'	System	01 Sep 2020 18:57:59

US3892042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:22:50

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 18:57:59

US3892042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:22:50

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered 'ONCE'	System	01 Sep 2020 18:57:59

US3892042

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:22:50

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 18:57:59

US3892042

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:14:55

US3892042

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '01 Sep 2020'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:14:55



**US3892042**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:22:50**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '12:28'	(b) (4) (b) (4), (b) (6)	01 Sep 2020 19:14:55

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:22:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered '01 Sep 2020 12:28'	System	01 Sep 2020 19:14:55

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 10:22:50**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '01 Sep 2020'	(b) (4) Andryelle Toledo (b) (4)	01 Sep 2020 22:17:11

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Andryelle Toledo (b) (4)	01 Sep 2020 22:17:11

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	01 Sep 2020 22:17:11

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '12:25'	(b) (4) Andryelle Toledo (b) (4)	01 Sep 2020 22:17:11

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered '01 Sep 2020 12:25'	System	01 Sep 2020 22:17:11

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Andryelle Toledo (b) (4)	01 Sep 2020 22:17:11



**US3892042**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	01 Sep 2020 22:17:11

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 10:22:50**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	01 Sep 2020 22:17:11

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered empty.	System	01 Sep 2020 22:17:11

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:22:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	01 Sep 2020 22:17:35

**US3892042**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:22:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered 'I'	System	01 Sep 2020 22:17:35

US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	01 Sep 2020 18:57:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 18:57:59

US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:22:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-01T13:28:36', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '819a6e90-0d10-4d7e-8476-b6fe89dfe916'	System	01 Sep 2020 19:28:54
User entered 'Yes (Y)'	System	01 Sep 2020 19:28:54

US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:22:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-01T13:28:43', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '819a6e90-0d10-4d7e-8476-b6fe89dfe916'	System	01 Sep 2020 19:28:54
User entered '97.0'	System	01 Sep 2020 19:28:54



US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-01T13:28:47', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '819a6e90-0d10-4d7e-8476-b6fe89dfe916'	System	01 Sep 2020 19:28:54
User entered 'No (N)'	System	01 Sep 2020 19:28:54

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-01T13:28:50', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '819a6e90-0d10-4d7e-8476-b6fe89dfe916'	System	01 Sep 2020 19:28:54
User entered '01 Sep 2020 13:28'	System	01 Sep 2020 19:28:54

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '01 Sep 2020 13:13'	System	01 Sep 2020 18:57:59

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '01 Sep 2020 15:43'	System	01 Sep 2020 18:57:59

US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	01 Sep 2020 18:57:59
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 18:57:59

US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:22:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-02T07:14:16', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '52e64a93-22c7-485d-9c70-48bb3be096ba'	System	02 Sep 2020 13:14:38
User entered 'Yes (Y)'	System	02 Sep 2020 13:14:38

US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:22:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-02T07:14:23', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '52e64a93-22c7-485d-9c70-48bb3be096ba' User entered '97.1'	System	02 Sep 2020 13:14:38
	System	02 Sep 2020 13:14:38

US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-02T07:14:27', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '52e64a93-22c7-485d-9c70-48bb3be096ba'	System	02 Sep 2020 13:14:38
User entered 'No (N)'	System	02 Sep 2020 13:14:38



**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-02T07:14:34', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '52e64a93-22c7-485d-9c70-48bb3be096ba'	System	02 Sep 2020 13:14:38
User entered '02 Sep 2020 07:14'	System	02 Sep 2020 13:14:38

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '01 Sep 2020 16:38'	System	01 Sep 2020 18:57:59

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 18:57:59

US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	01 Sep 2020 18:57:59
User entered 'Day 2'	System	01 Sep 2020 18:57:59

US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:22:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-02T18:31:35', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '0012059b-c0b8-490d-a5e3-24a8add34b01'	System	03 Sep 2020 00:31:50
User entered 'Yes (Y)'	System	03 Sep 2020 00:31:50

US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:22:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-02T18:31:40', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '0012059b-c0b8-490d-a5e3-24a8add34b01'	System	03 Sep 2020 00:31:50
User entered '97.6'	System	03 Sep 2020 00:31:50

US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-02T18:31:43', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '0012059b-c0b8-490d-a5e3-24a8add34b01'	System	03 Sep 2020 00:31:50
User entered 'No (N)'	System	03 Sep 2020 00:31:50

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-02T18:31:46', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '0012059b-c0b8-490d-a5e3-24a8add34b01'	System	03 Sep 2020 00:31:50
User entered '02 Sep 2020 18:31'	System	03 Sep 2020 00:31:50



**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 18:57:59

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 18:57:59

US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	01 Sep 2020 18:57:59
User entered 'Day 3'	System	01 Sep 2020 18:57:59

US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:22:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-03T13:00:33', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'bfc1105e-99a7-4ce5-9af5-fe457c814960'	System	03 Sep 2020 19:01:06
User entered 'Yes (Y)'	System	03 Sep 2020 19:01:06

US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:22:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-03T13:00:50', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'bfc1105e-99a7-4ce5-9af5-fe457c814960'	System	03 Sep 2020 19:01:06
User entered '97.4'	System	03 Sep 2020 19:01:06

US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-03T13:00:55', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'bfc1105e-99a7-4ce5-9af5-fe457c814960'	System	03 Sep 2020 19:01:06
User entered 'No (N)'	System	03 Sep 2020 19:01:06

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-03T13:00:59', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'bfc1105e-99a7-4ce5-9af5-fe457c814960'	System	03 Sep 2020 19:01:06
User entered '03 Sep 2020 13:00'	System	03 Sep 2020 19:01:06

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 18:57:59



**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 18:57:59

US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	01 Sep 2020 18:57:59
User entered 'Day 4'	System	01 Sep 2020 18:57:59

US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:22:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-04T12:34:59', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'b61c6472-b1a9-4271-a5f7-63ed96d19d6d'	System	04 Sep 2020 18:35:17
User entered 'Yes (Y)'	System	04 Sep 2020 18:35:17

US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:22:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-04T12:35:04', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'b61c6472-b1a9-4271-a5f7-63ed96d19d6d' User entered '97.1'	System	04 Sep 2020 18:35:17
	System	04 Sep 2020 18:35:17

US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-04T12:35:08', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'b61c6472-b1a9-4271-a5f7-63ed96d19d6d'	System	04 Sep 2020 18:35:17
User entered 'No (N)'	System	04 Sep 2020 18:35:17

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-04T12:35:10', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'b61c6472-b1a9-4271-a5f7-63ed96d19d6d'	System	04 Sep 2020 18:35:17
User entered '04 Sep 2020 12:35'	System	04 Sep 2020 18:35:17

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 18:57:59

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 18:57:59



US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	01 Sep 2020 18:57:59
User entered 'Day 5'	System	01 Sep 2020 18:57:59

US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:22:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-05T13:00:02', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '613f1d61-1118-4759-92fc-ac7a65fc60f0'	System	05 Sep 2020 19:00:25
User entered 'Yes (Y)'	System	05 Sep 2020 19:00:25

US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:22:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-05T13:00:10', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '613f1d61-1118-4759-92fc-ac7a65fc60f0' User entered '97.8'	System	05 Sep 2020 19:00:25
	System	05 Sep 2020 19:00:25

US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-05T13:00:14', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '613f1d61-1118-4759-92fc-ac7a65fc60f0'	System	05 Sep 2020 19:00:25
User entered 'No (N)'	System	05 Sep 2020 19:00:25

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-05T13:00:21', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '613f1d61-1118-4759-92fc-ac7a65fc60f0'	System	05 Sep 2020 19:00:25
User entered '05 Sep 2020 13:00'	System	05 Sep 2020 19:00:25

US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:22:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 18:57:59

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 18:57:59

US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	01 Sep 2020 18:57:59
User entered 'Day 6'	System	01 Sep 2020 18:57:59



US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:22:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26

US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:22:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26

US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26

US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26

US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:22:50

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26

US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:22:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 18:57:59

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 18:57:59



US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	01 Sep 2020 18:57:59
User entered 'Day 7'	System	01 Sep 2020 18:57:59

US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:22:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-07T22:27:14', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '42091c17-9af0-4eb0-9182-944b95b9dcfd'	System	08 Sep 2020 04:27:39
User entered 'Yes (Y)'	System	08 Sep 2020 04:27:39

US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:22:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-07T22:27:21', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '42091c17-9af0-4eb0-9182-944b95b9dcfd'	System	08 Sep 2020 04:27:39
User entered '97.1'	System	08 Sep 2020 04:27:39

US3892042

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-07T22:27:23', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '42091c17-9af0-4eb0-9182-944b95b9dcfd'	System	08 Sep 2020 04:27:39
User entered 'No (N)'	System	08 Sep 2020 04:27:39

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-07T22:27:26', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '42091c17-9af0-4eb0-9182-944b95b9dcfd'	System	08 Sep 2020 04:27:39
User entered '07 Sep 2020 22:27'	System	08 Sep 2020 04:27:39

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 18:57:59

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 18:57:59

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	01 Sep 2020 18:57:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 18:57:59



US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:22:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-01T13:25:51', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '913bb60a-af0e-4aa5-9d2a-a69497ff1812'	System	01 Sep 2020 19:28:31
User entered 'None (1)'	System	01 Sep 2020 19:28:31

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:22:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-01T13:28:10', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '913bb60a-af0e-4aa5-9d2a-a69497ff1812'	System	01 Sep 2020 19:28:31
User entered 'No (N)'	System	01 Sep 2020 19:28:31

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-01T13:28:15', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '913bb60a-af0e-4aa5-9d2a-a69497ff1812'	System	01 Sep 2020 19:28:31
User entered 'No (N)'	System	01 Sep 2020 19:28:31

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:22:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-01T13:28:20', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '913bb60a-af0e-4aa5-9d2a-a69497ff1812'	System	01 Sep 2020 19:28:31
User entered 'None (1)'	System	01 Sep 2020 19:28:31

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-01T13:28:27', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '913bb60a-af0e-4aa5-9d2a-a69497ff1812'	System	01 Sep 2020 19:28:31
User entered '01 Sep 2020 13:28'	System	01 Sep 2020 19:28:31

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '01 Sep 2020 13:13'	System	01 Sep 2020 18:57:59

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '01 Sep 2020 15:43'	System	01 Sep 2020 18:57:59

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	01 Sep 2020 18:57:59
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 18:57:59



US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:22:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-02T07:13:17', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '1c4ae55b-75a6-4dac-930d-70b092e10b0f'	System	02 Sep 2020 13:13:36
User entered 'Does not interfere with activity (2)'	System	02 Sep 2020 13:13:36

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:22:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-02T07:13:20', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '1c4ae55b-75a6-4dac-930d-70b092e10b0f'	System	02 Sep 2020 13:13:36
User entered 'No (N)'	System	02 Sep 2020 13:13:36

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-02T07:13:24', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '1c4ae55b-75a6-4dac-930d-70b092e10b0f'	System	02 Sep 2020 13:13:36
User entered 'No (N)'	System	02 Sep 2020 13:13:36

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:22:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-02T07:13:27', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '1c4ae55b-75a6-4dac-930d-70b092e10b0f'	System	02 Sep 2020 13:13:36
User entered 'None (1)'	System	02 Sep 2020 13:13:36

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-02T07:13:31', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '1c4ae55b-75a6-4dac-930d-70b092e10b0f'	System	02 Sep 2020 13:13:36
User entered '02 Sep 2020 07:13'	System	02 Sep 2020 13:13:36

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '01 Sep 2020 16:38'	System	01 Sep 2020 18:57:59

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 18:57:59

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	01 Sep 2020 18:57:59
User entered 'Day 2'	System	01 Sep 2020 18:57:59



US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:22:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-02T18:31:52', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '3b49fbcc-3e50-4ba8-bd78-ceee515669c4'	System	03 Sep 2020 13:10:03
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 13:10:03

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-02T18:31:55', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '3b49fbcc-3e50-4ba8-bd78-ceee515669c4'	System	03 Sep 2020 13:10:03
User entered 'No (N)'	System	03 Sep 2020 13:10:03

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-02T18:31:57', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '3b49fbcc-3e50-4ba8-bd78-cccc515669c4'	System	03 Sep 2020 13:10:03
User entered 'Yes (Y)'	System	03 Sep 2020 13:10:03

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:22:50

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-03T07:09:50', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '3b49fbcc-3e50-4ba8-bd78-ceee515669c4'	System	03 Sep 2020 13:10:03
User entered '80'	System	03 Sep 2020 13:10:03

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:22:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-03T07:09:55', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '3b49fbcc-3e50-4ba8-bd78-ceee515669c4'	System	03 Sep 2020 13:10:03
User entered 'None (1)'	System	03 Sep 2020 13:10:03

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-03T07:09:59', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '3b49fbcc-3e50-4ba8-bd78-ceee515669c4'	System	03 Sep 2020 13:10:03
User entered '03 Sep 2020 07:09'	System	03 Sep 2020 13:10:03

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 18:57:59

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 18:57:59



US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	01 Sep 2020 18:57:59
User entered 'Day 3'	System	01 Sep 2020 18:57:59

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:22:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-03T13:00:05', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '0de031c0-9ef2-4c0f-9b18-449375d0643e'	System	03 Sep 2020 19:00:36
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 19:00:36

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-03T13:00:08', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '0de031c0-9ef2-4c0f-9b18-449375d0643e'	System	03 Sep 2020 19:00:36
User entered 'No (N)'	System	03 Sep 2020 19:00:36

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-03T13:00:10', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '0de031c0-9ef2-4c0f-9b18-449375d0643e'	System	03 Sep 2020 19:00:36
User entered 'Yes (Y)'	System	03 Sep 2020 19:00:36

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:22:50

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-03T13:00:15', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '0de031c0-9ef2-4c0f-9b18-449375d0643e'	System	03 Sep 2020 19:00:36
User entered '80'	System	03 Sep 2020 19:00:36

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:22:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-03T13:00:22', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '0de031c0-9ef2-4c0f-9b18-449375d0643e'	System	03 Sep 2020 19:00:36
User entered 'None (1)'	System	03 Sep 2020 19:00:36

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-03T13:00:24', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '0de031c0-9ef2-4c0f-9b18-449375d0643e'	System	03 Sep 2020 19:00:36
User entered '03 Sep 2020 13:00'	System	03 Sep 2020 19:00:36

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 18:57:59



**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 18:57:59

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	01 Sep 2020 18:57:59
User entered 'Day 4'	System	01 Sep 2020 18:57:59

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:22:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-04T12:35:17', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'a1e40de4-5bc0-49bc-b77c-529f050dee2c'	System	04 Sep 2020 18:35:30
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 18:35:30

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:22:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-04T12:35:19', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'a1e40de4-5bc0-49bc-b77c-529f050dee2c'	System	04 Sep 2020 18:35:30
User entered 'No (N)'	System	04 Sep 2020 18:35:30

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-04T12:35:22', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'a1e40de4-5bc0-49bc-b77c-529f050dee2c'	System	04 Sep 2020 18:35:30
User entered 'No (N)'	System	04 Sep 2020 18:35:30

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:22:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-04T12:35:25', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'a1e40de4-5bc0-49bc-b77c-529f050dee2c'	System	04 Sep 2020 18:35:30
User entered 'None (1)'	System	04 Sep 2020 18:35:30

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-04T12:35:28', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'a1e40de4-5bc0-49bc-b77c-529f050dee2c'	System	04 Sep 2020 18:35:30
User entered '04 Sep 2020 12:35'	System	04 Sep 2020 18:35:30

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 18:57:59



**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 18:57:59

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	01 Sep 2020 18:57:59
User entered 'Day 5'	System	01 Sep 2020 18:57:59

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:22:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-05T13:00:27', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '7b6e0544-b103-4c2b-a7b7-412ca493b376'	System	05 Sep 2020 19:00:46
User entered 'None (1)'	System	05 Sep 2020 19:00:46

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-05T13:00:32', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '7b6e0544-b103-4c2b-a7b7-412ca493b376'	System	05 Sep 2020 19:00:46
User entered 'No (N)'	System	05 Sep 2020 19:00:46

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-05T13:00:34', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '7b6e0544-b103-4c2b-a7b7-412ca493b376'	System	05 Sep 2020 19:00:46
User entered 'No (N)'	System	05 Sep 2020 19:00:46

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:22:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-05T13:00:37', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '7b6e0544-b103-4c2b-a7b7-412ca493b376'	System	05 Sep 2020 19:00:46
User entered 'None (1)'	System	05 Sep 2020 19:00:46

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-05T13:00:41', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '7b6e0544-b103-4c2b-a7b7-412ca493b376'	System	05 Sep 2020 19:00:46
User entered '05 Sep 2020 13:00'	System	05 Sep 2020 19:00:46

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 18:57:59



**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 18:57:59

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	01 Sep 2020 18:57:59
User entered 'Day 6'	System	01 Sep 2020 18:57:59

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:22:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:22:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:22:50

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:22:50

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:22:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26



**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 18:57:59

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 18:57:59

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	01 Sep 2020 18:57:59
User entered 'Day 7'	System	01 Sep 2020 18:57:59

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:22:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-07T22:27:30', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '3fefc556-7530-48c2-9a7b-af76ea666611'	System	08 Sep 2020 04:27:50
User entered 'None (1)'	System	08 Sep 2020 04:27:50

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:22:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-07T22:27:32', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '3fefc556-7530-48c2-9a7b-af76ea666611'	System	08 Sep 2020 04:27:50
User entered 'No (N)'	System	08 Sep 2020 04:27:50

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-07T22:27:34', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '3fefc556-7530-48c2-9a7b-af76ea666611'	System	08 Sep 2020 04:27:50
User entered 'No (N)'	System	08 Sep 2020 04:27:50

US3892042

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:22:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-07T22:27:36', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '3fefc556-7530-48c2-9a7b-af76ea666611'	System	08 Sep 2020 04:27:50
User entered 'None (1)'	System	08 Sep 2020 04:27:50



**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-07T22:27:40', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '3fefc556-7530-48c2-9a7b-af76ea666611'	System	08 Sep 2020 04:27:50
User entered '07 Sep 2020 22:27'	System	08 Sep 2020 04:27:50

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 18:57:59

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 18:57:59

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	01 Sep 2020 18:57:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 18:57:59

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:22:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-01T13:28:59', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '86b768da-a700-4734-bd84-de4c58b963f8'	System	01 Sep 2020 19:29:37
User entered 'None (0)'	System	01 Sep 2020 19:29:37

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:22:50**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-01T13:29:05', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '86b768da-a700-4734-bd84-de4c58b963f8'	System	01 Sep 2020 19:29:37
User entered 'None (0)'	System	01 Sep 2020 19:29:37

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:22:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-01T13:29:09', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '86b768da-a700-4734-bd84-de4c58b963f8'	System	01 Sep 2020 19:29:37
User entered 'None (0)'	System	01 Sep 2020 19:29:37

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:22:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-01T13:29:14', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '86b768da-a700-4734-bd84-de4c58b963f8'	System	01 Sep 2020 19:29:37
User entered 'None (0)'	System	01 Sep 2020 19:29:37



**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:22:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-01T13:29:16', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '86b768da-a700-4734-bd84-de4c58b963f8'	System	01 Sep 2020 19:29:37
User entered 'None (0)'	System	01 Sep 2020 19:29:37

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:22:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-01T13:29:18', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '86b768da-a700-4734-bd84-de4c58b963f8'	System	01 Sep 2020 19:29:37
User entered 'None (0)'	System	01 Sep 2020 19:29:37

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-01T13:29:26', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '86b768da-a700-4734-bd84-de4c58b963f8'	System	01 Sep 2020 19:29:37
User entered 'No (N)'	System	01 Sep 2020 19:29:37

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-01T13:29:30', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '86b768da-a700-4734-bd84-de4c58b963f8'	System	01 Sep 2020 19:29:37
User entered '01 Sep 2020 13:29'	System	01 Sep 2020 19:29:37

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '01 Sep 2020 13:13'	System	01 Sep 2020 18:57:59

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '01 Sep 2020 15:43'	System	01 Sep 2020 18:57:59

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	01 Sep 2020 18:57:59
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 18:57:59

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:22:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-02T07:13:36', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '8e13113d-2efe-45f1-bef1-40851160bb39'	System	02 Sep 2020 13:14:17
User entered 'None (0)'	System	02 Sep 2020 13:14:17



**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:22:50**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-02T07:13:41', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '8e13113d-2efe-45f1-bef1-40851160bb39'	System	02 Sep 2020 13:14:17
User entered 'None (0)'	System	02 Sep 2020 13:14:17

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:22:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-02T07:13:49', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '8e13113d-2efe-45f1-bef1-40851160bb39'	System	02 Sep 2020 13:14:17
User entered 'None (0)'	System	02 Sep 2020 13:14:17

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:22:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-02T07:13:57', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '8e13113d-2efe-45f1-bef1-40851160bb39'	System	02 Sep 2020 13:14:17
User entered 'None (0)'	System	02 Sep 2020 13:14:17

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:22:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-02T07:13:59', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '8e13113d-2efe-45f1-bef1-40851160bb39'	System	02 Sep 2020 13:14:17
User entered 'None (0)'	System	02 Sep 2020 13:14:17

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:22:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-02T07:14:01', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '8e13113d-2efe-45f1-bef1-40851160bb39'	System	02 Sep 2020 13:14:17
User entered 'None (0)'	System	02 Sep 2020 13:14:17

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-02T07:14:05', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '8e13113d-2efe-45f1-bef1-40851160bb39'	System	02 Sep 2020 13:14:17
User entered 'No (N)'	System	02 Sep 2020 13:14:17

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-02T07:14:10', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '8e13113d-2efe-45f1-bef1-40851160bb39'	System	02 Sep 2020 13:14:17
User entered '02 Sep 2020 07:14'	System	02 Sep 2020 13:14:17

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '01 Sep 2020 16:38'	System	01 Sep 2020 18:57:59



**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 18:57:59

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	01 Sep 2020 18:57:59
User entered 'Day 2'	System	01 Sep 2020 18:57:59

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:22:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-03T07:10:03', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '2665ca39-5581-46ae-ad9e-e82d7d6c5386'	System	03 Sep 2020 13:11:13
User entered 'None (0)'	System	03 Sep 2020 13:11:13

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:22:50**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-03T07:10:05', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '2665ca39-5581-46ae-ad9e-e82d7d6c5386'	System	03 Sep 2020 13:11:13
User entered 'None (0)'	System	03 Sep 2020 13:11:13

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:22:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-03T07:10:06', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '2665ca39-5581-46ae-ad9e-e82d7d6c5386'	System	03 Sep 2020 13:11:13
User entered 'None (0)'	System	03 Sep 2020 13:11:13

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:22:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-03T07:10:10', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '2665ca39-5581-46ae-ad9e-e82d7d6c5386'	System	03 Sep 2020 13:11:13
User entered 'None (0)'	System	03 Sep 2020 13:11:13

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:22:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-03T07:10:12', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '2665ca39-5581-46ae-ad9e-e82d7d6c5386'	System	03 Sep 2020 13:11:13
User entered 'None (0)'	System	03 Sep 2020 13:11:13

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:22:50

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-03T07:10:14', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '2665ca39-5581-46ae-ad9e-e82d7d6c5386'	System	03 Sep 2020 13:11:13
User entered 'None (0)'	System	03 Sep 2020 13:11:13



US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-03T07:11:04', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '2665ca39-5581-46ae-ad9e-e82d7d6c5386'	System	03 Sep 2020 13:11:13
User entered 'No (N)'	System	03 Sep 2020 13:11:13

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-03T07:11:07', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '2665ca39-5581-46ae-ad9e-e82d7d6c5386'	System	03 Sep 2020 13:11:13
User entered '03 Sep 2020 07:11'	System	03 Sep 2020 13:11:13

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 18:57:59

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 18:57:59

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	01 Sep 2020 18:57:59
User entered 'Day 3'	System	01 Sep 2020 18:57:59

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:22:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-03T12:59:41', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '24e32ae6-93d4-4b17-8de8-293180020cf3'	System	03 Sep 2020 19:00:08
User entered 'None (0)'	System	03 Sep 2020 19:00:08

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:22:50**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-03T12:59:43', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '24e32ae6-93d4-4b17-8de8-293180020cf3'	System	03 Sep 2020 19:00:08
User entered 'None (0)'	System	03 Sep 2020 19:00:08

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:22:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-03T12:59:48', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '24e32ae6-93d4-4b17-8de8-293180020cf3'	System	03 Sep 2020 19:00:08
User entered 'None (0)'	System	03 Sep 2020 19:00:08



US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:22:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-03T12:59:51', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '24e32ae6-93d4-4b17-8de8-293180020cf3'	System	03 Sep 2020 19:00:08
User entered 'None (0)'	System	03 Sep 2020 19:00:08

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:22:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-03T12:59:53', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '24e32ae6-93d4-4b17-8de8-293180020cf3'	System	03 Sep 2020 19:00:08
User entered 'None (0)'	System	03 Sep 2020 19:00:08

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:22:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-03T12:59:55', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '24e32ae6-93d4-4b17-8de8-293180020cf3'	System	03 Sep 2020 19:00:08
User entered 'None (0)'	System	03 Sep 2020 19:00:08

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-03T12:59:58', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '24e32ae6-93d4-4b17-8de8-293180020cf3'	System	03 Sep 2020 19:00:08
User entered 'No (N)'	System	03 Sep 2020 19:00:08

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-03T13:00:01', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '24e32ae6-93d4-4b17-8de8-293180020cf3'	System	03 Sep 2020 19:00:08
User entered '03 Sep 2020 13:00'	System	03 Sep 2020 19:00:08

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 18:57:59

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 18:57:59

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	01 Sep 2020 18:57:59
User entered 'Day 4'	System	01 Sep 2020 18:57:59



**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:22:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-04T12:35:31', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '38c3d39c-737c-4c14-ab23-d7cab2b5d9fb'	System	04 Sep 2020 18:35:50
User entered 'None (0)'	System	04 Sep 2020 18:35:50

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:22:50**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-04T12:35:33', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '38c3d39c-737c-4c14-ab23-d7cab2b5d9fb'	System	04 Sep 2020 18:35:50
User entered 'None (0)'	System	04 Sep 2020 18:35:50

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:22:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-04T12:35:35', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '38c3d39c-737c-4c14-ab23-d7cab2b5d9fb'	System	04 Sep 2020 18:35:50
User entered 'None (0)'	System	04 Sep 2020 18:35:50

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:22:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-04T12:35:37', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '38c3d39c-737c-4c14-ab23-d7cab2b5d9fb'	System	04 Sep 2020 18:35:50
User entered 'None (0)'	System	04 Sep 2020 18:35:50

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:22:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-04T12:35:39', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '38c3d39c-737c-4c14-ab23-d7cab2b5d9fb'	System	04 Sep 2020 18:35:50
User entered 'None (0)'	System	04 Sep 2020 18:35:50

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:22:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-04T12:35:41', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '38c3d39c-737c-4c14-ab23-d7cab2b5d9fb'	System	04 Sep 2020 18:35:50
User entered 'None (0)'	System	04 Sep 2020 18:35:50

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-04T12:35:44', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '38c3d39c-737c-4c14-ab23-d7cab2b5d9fb'	System	04 Sep 2020 18:35:50
User entered 'No (N)'	System	04 Sep 2020 18:35:50

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-04T12:35:47', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '38c3d39c-737c-4c14-ab23-d7cab2b5d9fb'	System	04 Sep 2020 18:35:50
User entered '04 Sep 2020 12:35'	System	04 Sep 2020 18:35:50



**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 18:57:59

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 18:57:59

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	01 Sep 2020 18:57:59
User entered 'Day 5'	System	01 Sep 2020 18:57:59

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:22:50

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-05T13:01:07', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '85fa8458-8218-46c5-82f0-e62382f5fe58'	System	05 Sep 2020 19:01:40
User entered 'None (0)'	System	05 Sep 2020 19:01:40

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:22:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-05T13:01:11', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '85fa8458-8218-46c5-82f0-e62382f5fe58'	System	05 Sep 2020 19:01:40
User entered 'None (0)'	System	05 Sep 2020 19:01:40

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:22:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-05T13:01:14', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '85fa8458-8218-46c5-82f0-e62382f5fe58'	System	05 Sep 2020 19:01:40
User entered 'None (0)'	System	05 Sep 2020 19:01:40

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:22:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-05T13:01:18', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '85fa8458-8218-46c5-82f0-e62382f5fe58'	System	05 Sep 2020 19:01:40
User entered 'None (0)'	System	05 Sep 2020 19:01:40

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 10:22:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-05T13:01:21', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '85fa8458-8218-46c5-82f0-e62382f5fe58'	System	05 Sep 2020 19:01:40
User entered 'None (0)'	System	05 Sep 2020 19:01:40



US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:22:50

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-05T13:01:26', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '85fa8458-8218-46c5-82f0-e62382f5fe58'	System	05 Sep 2020 19:01:40
User entered 'None (0)'	System	05 Sep 2020 19:01:40

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-05T13:01:34', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '85fa8458-8218-46c5-82f0-e62382f5fe58'	System	05 Sep 2020 19:01:40
User entered 'No (N)'	System	05 Sep 2020 19:01:40

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-05T13:01:37', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '85fa8458-8218-46c5-82f0-e62382f5fe58'	System	05 Sep 2020 19:01:40
User entered '05 Sep 2020 13:01'	System	05 Sep 2020 19:01:40

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 18:57:59

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 18:57:59

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	01 Sep 2020 18:57:59
User entered 'Day 6'	System	01 Sep 2020 18:57:59

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:22:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:22:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26



US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:22:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:22:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:22:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:22:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:22:50

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 18:57:59

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 18:57:59



US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	01 Sep 2020 18:57:59
User entered 'Day 7'	System	01 Sep 2020 18:57:59

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:22:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-07T22:27:47', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'a021dccf-c0a4-4504-ba0f-8efb61d0f18e'	System	08 Sep 2020 04:28:11
User entered 'None (0)'	System	08 Sep 2020 04:28:11

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:22:50**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-07T22:27:49', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'a021dccf-c0a4-4504-ba0f-8efb61d0f18e'	System	08 Sep 2020 04:28:11
User entered 'None (0)'	System	08 Sep 2020 04:28:11

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:22:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-07T22:27:51', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'a021dccf-c0a4-4504-ba0f-8efb61d0f18e'	System	08 Sep 2020 04:28:11
User entered 'None (0)'	System	08 Sep 2020 04:28:11

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:22:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-07T22:27:53', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'a021dccf-c0a4-4504-ba0f-8efb61d0f18e'	System	08 Sep 2020 04:28:11
User entered 'None (0)'	System	08 Sep 2020 04:28:11

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:22:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-07T22:27:55', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'a021dccf-c0a4-4504-ba0f-8efb61d0f18e'	System	08 Sep 2020 04:28:11
User entered 'None (0)'	System	08 Sep 2020 04:28:11

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:22:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-07T22:27:57', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'a021dccf-c0a4-4504-ba0f-8efb61d0f18e'	System	08 Sep 2020 04:28:11
User entered 'None (0)'	System	08 Sep 2020 04:28:11

US3892042

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-07T22:28:01', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'a021dccf-c0a4-4504-ba0f-8efb61d0f18e'	System	08 Sep 2020 04:28:11
User entered 'No (N)'	System	08 Sep 2020 04:28:11



**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-07T22:28:04', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'a021dccf-c0a4-4504-ba0f-8efb61d0f18e'	System	08 Sep 2020 04:28:11
User entered '07 Sep 2020 22:28'	System	08 Sep 2020 04:28:11

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 18:57:59

**US3892042**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 18:57:59

**US3892042**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:22:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Yes (Y)'	(b) (4) Stefanie Vasconez (b) (4)	16 Sep 2020 21:15:40

US3892042

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	16 Sep 2020 21:15:57
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	16 Sep 2020 21:15:57
User entered '08 Sep 2020' reason for change: Data Entry Error	Stefanie Vasconez (b) (4)	16 Sep 2020 21:15:57
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	16 Sep 2020 21:15:40
User entered '16 Sep 2020'	System	16 Sep 2020 21:15:40
	Stefanie Vasconez (b) (4)	16 Sep 2020 21:15:40
	(b) (4)	

**US3892042**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:22:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stefanie Vasconez (b) (4)	16 Sep 2020 21:15:40

**US3892042**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:22:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered empty.	Stefanie Vasconez (b) (4)	16 Sep 2020 21:15:40

**US3892042**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:22:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Yes (Y)'	Stefanie Vasconez (b) (4)	16 Sep 2020 21:16:03



**US3892042**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:22:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered 'I'	System	16 Sep 2020 21:16:03

**US3892042**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:22:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:47
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Yes (Y)'	(b) (4) Stefanie Vasconez (b) (4)	16 Sep 2020 21:16:18

**US3892042**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:22:50**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:47
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '16 Sep 2020'	(b) (4) Stefanie Vasconez (b) (4)	16 Sep 2020 21:16:18

**US3892042**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:22:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:47
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Contact Made (CONTACT MADE)'	Stefanie Vasconez (b) (4)	16 Sep 2020 21:16:18

**US3892042**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:22:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:47
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered empty.	Stefanie Vasconez (b) (4)	16 Sep 2020 21:16:18

**US3892042**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:22:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:47
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Yes (Y)'	(b) (4) Stefanie Vasconez (b) (4)	16 Sep 2020 21:16:22

**US3892042**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:22:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:47
User entered 'I'	System	16 Sep 2020 21:16:22

**US3892042**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:22:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:47
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Yes (Y)'	(b) (4) Stefanie Vasconez (b) (4)	22 Sep 2020 21:59:17



**US3892042**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:22:50**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:47
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '22 Sep 2020'	(b) (4) Stefanie Vasconez (b) (4)	22 Sep 2020 21:59:17

**US3892042**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:22:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:47
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stefanie Vasconez (b) (4)	22 Sep 2020 21:59:17

**US3892042**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:22:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:47
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered empty.	Stefanie Vasconez (b) (4)	22 Sep 2020 21:59:17

**US3892042**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:22:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:47
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Yes (Y)'	(b) (4) Stefanie Vasconez (b) (4)	22 Sep 2020 22:09:46

**US3892042**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:22:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:47
User entered 'I'	System	22 Sep 2020 22:09:46

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:22:50**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 14:36:08

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '28 Sep 2020'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 14:36:08

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Clinic (Clinic)'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 14:36:08



**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:22:50**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered 'VISIT2'	System	28 Sep 2020 14:36:08

US3892042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User accepted default value 'Pre-Dose (PREDOSE)'	Andryelle Toledo (b) (4)	28 Sep 2020 15:26:15
	(b) (4)	

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 15:26:15

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:22:50**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '28 Sep 2020'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 15:26:15

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '07:10'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 15:26:15

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered '28 Sep 2020 07:10'	System	28 Sep 2020 15:26:15

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '98.1' F	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 15:26:15

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Oral (Oral)'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 15:26:15



**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:22:50**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 15:26:15

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '63'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 15:26:15

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered 'bpm'	System	28 Sep 2020 15:26:15

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '12'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 15:26:15

US3892042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:22:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered 'breaths/min'	System	28 Sep 2020 15:26:15

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '127'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 15:26:15

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered 'mmHg'	System	28 Sep 2020 15:26:15

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '78'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 15:26:15



**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered 'mmHg'	System	28 Sep 2020 15:26:15

US3892042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:50

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User accepted default value 'Post-Dose (POSTDOSE)'	Andryelle Toledo (b) (4) (b) (4)	28 Sep 2020 15:26:15

US3892042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:50

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 15:26:15

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:22:50**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '28 Sep 2020'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 15:26:15

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '08:47'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 15:26:15

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered '28 Sep 2020 08:47'	System	28 Sep 2020 15:26:15

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '97.1' F	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 15:26:15

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Oral (Oral)'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 15:26:15



**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:22:50**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 15:26:15

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '58'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 15:26:15

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered 'bpm'	System	28 Sep 2020 15:26:15

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '12'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 15:26:15

US3892042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:50

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered 'breaths/min'	System	28 Sep 2020 15:26:15

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '117'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 15:26:15

US3892042

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:22:50

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered 'mmHg'	System	28 Sep 2020 15:26:15

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '77'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 15:26:15



**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered 'mmHg'	System	28 Sep 2020 15:26:15

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 10:22:50**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 15:27:06

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 10:22:50**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '28 Sep 2020'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 15:27:06

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:22:50**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 14:36:34

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:22:50**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 14:36:34

US3892042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered empty.	Andryelle Toledo (b) (4)	28 Sep 2020 14:36:34

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:22:50**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered 'MRNA-1273 OR PLACEBO'	System	28 Sep 2020 14:36:34

US3892042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:50

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '28 Sep 2020'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 14:36:34



**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:22:50**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '08:14'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 14:36:34

US3892042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:50

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered '28 Sep 2020 08:14'	System	28 Sep 2020 14:36:34

US3892042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:50

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Left Arm (LEFT ARM)'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 14:36:34

US3892042

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:22:50

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered 'ONCE'	System	28 Sep 2020 14:36:34

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:22:50**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered 'INTRAMUSCULAR'	System	28 Sep 2020 14:36:34

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:22:50**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 15:27:35

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:22:50**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '28 Sep 2020'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 15:27:35

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:22:50**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '07:23'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 15:27:35



**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:22:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered '28 Sep 2020 07:23'	System	28 Sep 2020 15:27:35

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 10:22:50**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '28 Sep 2020'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 15:27:55

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Andryelle Toledo (b) (4) (b) (4)	28 Sep 2020 15:27:55

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	13 Oct 2020 18:24:07
User entered 'No (N)'	Andryelle Toledo (b) (4)	28 Sep 2020 15:27:55
	(b) (4)	

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 10:22:50**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '07:28' reason for change: Data Entry Error	(b) (4)	13 Oct 2020 18:24:07
User entered empty.	Andryelle Toledo (b) (4)	28 Sep 2020 15:27:55
	(b) (4)	

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered '28 Sep 2020 07:28'	System	13 Oct 2020 18:24:07
User entered empty.	System	28 Sep 2020 15:27:55

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Andryelle Toledo (b) (4)	28 Sep 2020 15:27:55

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	13 Oct 2020 18:24:07
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	28 Sep 2020 15:27:55
	(b) (4)	



**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered empty; reason for change Data Entry Error	(b) (4)	13 Oct 2020 18:24:07
User entered '07:28'	Andryelle Toledo (b) (4)	28 Sep 2020 15:27:55
	(b) (4)	

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered empty.	System	13 Oct 2020 18:24:07
User entered '28 Sep 2020 07:28'	System	28 Sep 2020 15:27:55

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:22:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	28 Sep 2020 15:28:14

**US3892042**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:22:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered 'I'	System	28 Sep 2020 15:28:14

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	28 Sep 2020 14:36:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 14:36:34

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:22:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-28T08:49:01', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '22f694a6-78e8-4b1e-a379-2d4b7b03b198'	System	28 Sep 2020 14:49:21
User entered 'Yes (Y)'	System	28 Sep 2020 14:49:21

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:22:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-28T08:49:07', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '22f694a6-78e8-4b1e-a379-2d4b7b03b198'	System	28 Sep 2020 14:49:21
User entered '97.1'	System	28 Sep 2020 14:49:21

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-28T08:49:11', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '22f694a6-78e8-4b1e-a379-2d4b7b03b198'	System	28 Sep 2020 14:49:21
User entered 'No (N)'	System	28 Sep 2020 14:49:21



**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-28T08:49:14', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '22f694a6-78e8-4b1e-a379-2d4b7b03b198'	System	28 Sep 2020 14:49:21
User entered '28 Sep 2020 08:49'	System	28 Sep 2020 14:49:21

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '28 Sep 2020 08:34'	System	28 Sep 2020 14:36:34

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '28 Sep 2020 11:04'	System	28 Sep 2020 14:36:34

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	28 Sep 2020 14:36:34
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 14:36:34

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:22:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-29T03:29:39', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '296baf37-4ea7-4d29-b48e-1cdce1bc91f1'	System	29 Sep 2020 09:30:26
User entered 'Yes (Y)'	System	29 Sep 2020 09:30:26

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:22:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-29T03:29:49', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '296baf37-4ea7-4d29-b48e-1cdce1bc91f1'	System	29 Sep 2020 09:30:26
User entered '98.4'	System	29 Sep 2020 09:30:26

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-29T03:29:53', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '296baf37-4ea7-4d29-b48e-1cdce1bc91f1'	System	29 Sep 2020 09:30:26
User entered 'No (N)'	System	29 Sep 2020 09:30:26

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-29T03:29:56', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '296baf37-4ea7-4d29-b48e-1cdce1bc91f1'	System	29 Sep 2020 09:30:26
User entered '29 Sep 2020 03:29'	System	29 Sep 2020 09:30:26



**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '28 Sep 2020 11:59'	System	28 Sep 2020 14:36:34

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 14:36:34

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	28 Sep 2020 14:36:34
User entered 'Day 2'	System	28 Sep 2020 14:36:34

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:22:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-29T15:23:43', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'd87359ec-ca6a-4a3d-90ae-de9c441156e3'	System	29 Sep 2020 21:24:20
User entered 'Yes (Y)'	System	29 Sep 2020 21:24:20

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:22:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-29T15:23:53', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'd87359ec-ca6a-4a3d-90ae-de9c441156e3'	System	29 Sep 2020 21:24:20
User entered '99.0'	System	29 Sep 2020 21:24:20

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-29T15:23:58', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'd87359ec-ca6a-4a3d-90ae-de9c441156e3'	System	29 Sep 2020 21:24:20
User entered 'Yes (Y)'	System	29 Sep 2020 21:24:20

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted and medication recorded' (Site from System).	(b) (4), (b) (6)	08 Dec 2020 06:55:43
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-29T15:24:07', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'd87359ec-ca6a-4a3d-90ae-de9c441156e3'	Courtney Jensen (b) (4)	07 Dec 2020 20:28:32
User entered '1'	System	29 Sep 2020 21:24:20
	System	29 Sep 2020 21:24:20
	System	29 Sep 2020 21:24:20

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:22:50

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-29T15:24:07', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'd87359ec-ca6a-4a3d-90ae-de9c441156e3'	System	29 Sep 2020 21:24:20
User entered '0'	System	29 Sep 2020 21:24:20



**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-29T15:24:16', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'd87359ec-ca6a-4a3d-90ae-de9c441156e3'	System	29 Sep 2020 21:24:20
User entered '29 Sep 2020 15:24'	System	29 Sep 2020 21:24:20

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 14:36:34

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 14:36:34

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	28 Sep 2020 14:36:34
User entered 'Day 3'	System	28 Sep 2020 14:36:34

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:22:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-09-30T16:17:43', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '322e42cf-d766-40f3-b5ad-a1847e4202fe'	System	30 Sep 2020 22:18:11
User entered 'Yes (Y)'	System	30 Sep 2020 22:18:11

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:22:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-09-30T16:17:51', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '322e42cf-d766-40f3-b5ad-a1847e4202fe' User entered '97.7'	System	30 Sep 2020 22:18:11
	System	30 Sep 2020 22:18:11

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-09-30T16:17:56', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '322e42cf-d766-40f3-b5ad-a1847e4202fe'	System	30 Sep 2020 22:18:11
User entered 'Yes (Y)'	System	30 Sep 2020 22:18:11

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Participant contacted and medication recorded.' (Site from System).	(b) (4), (b) (6)	08 Dec 2020 06:55:50
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Courtney Jensen (b) (4)	07 Dec 2020 20:29:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-09-30T16:18:04', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '322e42cf-d766-40f3-b5ad-a1847e4202fe'	(b) (4)	
User entered '1'	System	30 Sep 2020 22:18:11
	System	30 Sep 2020 22:18:11
	System	30 Sep 2020 22:18:11



US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:22:50

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-09-30T16:18:04', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '322e42cf-d766-40f3-b5ad-a1847e4202fe' User entered '0'	System	30 Sep 2020 22:18:11
	System	30 Sep 2020 22:18:11

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-09-30T16:18:07', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '322e42cf-d766-40f3-b5ad-a1847e4202fe'	System	30 Sep 2020 22:18:11
User entered '30 Sep 2020 16:18'	System	30 Sep 2020 22:18:11

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 14:36:34

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 14:36:34

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	28 Sep 2020 14:36:34
User entered 'Day 4'	System	28 Sep 2020 14:36:34

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:22:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-01T12:33:17', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '7ebcba43-41d2-4459-80c1-914e09dcc501'	System	01 Oct 2020 18:33:33
User entered 'Yes (Y)'	System	01 Oct 2020 18:33:33

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:22:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-01T12:33:22', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '7ebcba43-41d2-4459-80c1-914e09dcc501'	System	01 Oct 2020 18:33:33
User entered '98.3'	System	01 Oct 2020 18:33:33

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-01T12:33:25', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '7ebcba43-41d2-4459-80c1-914e09dcc501'	System	01 Oct 2020 18:33:33
User entered 'No (N)'	System	01 Oct 2020 18:33:33



**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-01T12:33:28', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '7ebcba43-41d2-4459-80c1-914e09dcc501'	System	01 Oct 2020 18:33:33
User entered '01 Oct 2020 12:33'	System	01 Oct 2020 18:33:33

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:22:50

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 14:36:34

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 14:36:34

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	28 Sep 2020 14:36:34
User entered 'Day 5'	System	28 Sep 2020 14:36:34

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:22:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-03T06:35:32', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '2afd8168-ba48-4e23-a2d7-4abebb3a2295'	System	03 Oct 2020 12:35:50
User entered 'Yes (Y)'	System	03 Oct 2020 12:35:50

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:22:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-03T06:35:38', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '2afd8168-ba48-4e23-a2d7-4abebb3a2295'	System	03 Oct 2020 12:35:50
User entered '96.8'	System	03 Oct 2020 12:35:50

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-03T06:35:41', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '2afd8168-ba48-4e23-a2d7-4abebb3a2295'	System	03 Oct 2020 12:35:50
User entered 'No (N)'	System	03 Oct 2020 12:35:50

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:22:50

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-03T06:35:44', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '2afd8168-ba48-4e23-a2d7-4abebb3a2295'	System	03 Oct 2020 12:35:50
User entered '03 Oct 2020 06:35'	System	03 Oct 2020 12:35:50



**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 14:36:34

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 14:36:34

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	28 Sep 2020 14:36:34
User entered 'Day 6'	System	28 Sep 2020 14:36:34

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:22:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-03T22:41:36', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'e0dbdde9-8ce0-4f98-a83b-945283a2124d'	System	04 Oct 2020 04:41:51
User entered 'Yes (Y)'	System	04 Oct 2020 04:41:51

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:22:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-03T22:41:42', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'e0dbdde9-8ce0-4f98-a83b-945283a2124d'	System	04 Oct 2020 04:41:51
User entered '97.1'	System	04 Oct 2020 04:41:51

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-03T22:41:45', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'e0dbdde9-8ce0-4f98-a83b-945283a2124d'	System	04 Oct 2020 04:41:51
User entered 'No (N)'	System	04 Oct 2020 04:41:51

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-03T22:41:47', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'e0dbdde9-8ce0-4f98-a83b-945283a2124d'	System	04 Oct 2020 04:41:51
User entered '03 Oct 2020 22:41'	System	04 Oct 2020 04:41:51

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 14:36:34



**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 14:36:34

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	28 Sep 2020 14:36:34
User entered 'Day 7'	System	28 Sep 2020 14:36:34

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:22:50

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-04T12:19:44', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'da63eea3-ae66-4450-8b6a-d2883eb698a3'	System	04 Oct 2020 18:19:58
User entered 'Yes (Y)'	System	04 Oct 2020 18:19:58

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:22:50

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-04T12:19:49', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'da63eea3-ae66-4450-8b6a-d2883eb698a3'	System	04 Oct 2020 18:19:58
User entered '97.6'	System	04 Oct 2020 18:19:58

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-04T12:19:52', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'da63eea3-ae66-4450-8b6a-d2883eb698a3'	System	04 Oct 2020 18:19:58
User entered 'No (N)'	System	04 Oct 2020 18:19:58

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-04T12:19:54', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'da63eea3-ae66-4450-8b6a-d2883eb698a3'	System	04 Oct 2020 18:19:58
User entered '04 Oct 2020 12:19'	System	04 Oct 2020 18:19:58

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 14:36:34

US3892042

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:22:50

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 14:36:34



US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	28 Sep 2020 14:36:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 14:36:34

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:22:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-28T08:49:18', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '3b527fcd-31b1-470a-99e3-8ba77412109c'	System	28 Sep 2020 14:49:39
User entered 'None (1)'	System	28 Sep 2020 14:49:39

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:22:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-28T08:49:26', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '3b527fcd-31b1-470a-99e3-8ba77412109c'	System	28 Sep 2020 14:49:39
User entered 'No (N)'	System	28 Sep 2020 14:49:39

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-28T08:49:28', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '3b527fcd-31b1-470a-99e3-8ba77412109c'	System	28 Sep 2020 14:49:39
User entered 'No (N)'	System	28 Sep 2020 14:49:39

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:22:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-28T08:49:31', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '3b527fcd-31b1-470a-99e3-8ba77412109c'	System	28 Sep 2020 14:49:39
User entered 'None (1)'	System	28 Sep 2020 14:49:39

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-28T08:49:34', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '3b527fcd-31b1-470a-99e3-8ba77412109c'	System	28 Sep 2020 14:49:39
User entered '28 Sep 2020 08:49'	System	28 Sep 2020 14:49:39

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '28 Sep 2020 08:34'	System	28 Sep 2020 14:36:34

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '28 Sep 2020 11:04'	System	28 Sep 2020 14:36:34



US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	28 Sep 2020 14:36:34
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 14:36:34

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:22:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-29T03:30:04', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '77a73c7d-d38a-46cb-ad44-bc3df669f6a9'	System	29 Sep 2020 09:30:29
User entered 'Does not interfere with activity (2)'	System	29 Sep 2020 09:30:29

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:22:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-29T03:30:08', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '77a73c7d-d38a-46cb-ad44-bc3df669f6a9'	System	29 Sep 2020 09:30:29
User entered 'No (N)'	System	29 Sep 2020 09:30:29

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-29T03:30:11', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '77a73c7d-d38a-46cb-ad44-bc3df669f6a9'	System	29 Sep 2020 09:30:29
User entered 'No (N)'	System	29 Sep 2020 09:30:29

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:22:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-29T03:30:15', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '77a73c7d-d38a-46cb-ad44-bc3df669f6a9'	System	29 Sep 2020 09:30:29
User entered 'None (1)'	System	29 Sep 2020 09:30:29

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-29T03:30:24', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '77a73c7d-d38a-46cb-ad44-bc3df669f6a9'	System	29 Sep 2020 09:30:29
User entered '29 Sep 2020 03:30'	System	29 Sep 2020 09:30:29

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '28 Sep 2020 11:59'	System	28 Sep 2020 14:36:34

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 14:36:34



US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	28 Sep 2020 14:36:34
User entered 'Day 2'	System	28 Sep 2020 14:36:34

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:22:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-29T15:25:28', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'ff03daff-7a16-4b72-8df5-e94b4aead386'	System	29 Sep 2020 21:26:53
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	29 Sep 2020 21:26:53

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-29T15:25:31', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'ff03daff-7a16-4b72-8df5-e94b4aeced386'	System	29 Sep 2020 21:26:53
User entered 'No (N)'	System	29 Sep 2020 21:26:53

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-29T15:25:40', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'ff03daff-7a16-4b72-8df5-e94b4aeced386'	System	29 Sep 2020 21:26:53
User entered 'Yes (Y)'	System	29 Sep 2020 21:26:53

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:22:50

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-29T15:26:38', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'ff03daff-7a16-4b72-8df5-e94b4aead386'	System	29 Sep 2020 21:26:53
User entered '65'	System	29 Sep 2020 21:26:53

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:22:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-29T15:26:43', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'ff03daff-7a16-4b72-8df5-e94b4aead386'	System	29 Sep 2020 21:26:53
User entered 'None (1)'	System	29 Sep 2020 21:26:53

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-29T15:26:48', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'ff03daff-7a16-4b72-8df5-e94b4aeced386'	System	29 Sep 2020 21:26:53
User entered '29 Sep 2020 15:26'	System	29 Sep 2020 21:26:53

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 14:36:34



**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 14:36:34

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	28 Sep 2020 14:36:34
User entered 'Day 3'	System	28 Sep 2020 14:36:34

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:22:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-09-30T16:18:12', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '0db67bcc-ece4-4a70-81cd-bf78b90c54ce'	System	30 Sep 2020 22:18:33
User entered 'Does not interfere with activity (2)'	System	30 Sep 2020 22:18:33

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:22:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-09-30T16:18:15', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '0db67bcc-ece4-4a70-81cd-bf78b90c54ce'	System	30 Sep 2020 22:18:33
User entered 'No (N)'	System	30 Sep 2020 22:18:33

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-09-30T16:18:17', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '0db67bcc-ece4-4a70-81cd-bf78b90c54ce'	System	30 Sep 2020 22:18:33
User entered 'Yes (Y)'	System	30 Sep 2020 22:18:33

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:22:50

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-09-30T16:18:22', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '0db67bcc-ece4-4a70-81cd-bf78b90c54ce'	System	30 Sep 2020 22:18:33
User entered '50'	System	30 Sep 2020 22:18:33

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:22:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-09-30T16:18:25', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '0db67bcc-ece4-4a70-81cd-bf78b90c54ce'	System	30 Sep 2020 22:18:33
User entered 'None (1)'	System	30 Sep 2020 22:18:33

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-09-30T16:18:28', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '0db67bcc-ece4-4a70-81cd-bf78b90c54ce'	System	30 Sep 2020 22:18:33
User entered '30 Sep 2020 16:18'	System	30 Sep 2020 22:18:33



**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 14:36:34

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 14:36:34

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	28 Sep 2020 14:36:34
User entered 'Day 4'	System	28 Sep 2020 14:36:34

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:22:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-01T12:33:33', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '4ab60aa1-4969-45fa-af76-c1a8e69944c7'	System	01 Oct 2020 18:33:47
User entered 'Does not interfere with activity (2)'	System	01 Oct 2020 18:33:47

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:22:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-01T12:33:36', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '4ab60aa1-4969-45fa-af76-c1a8e69944c7'	System	01 Oct 2020 18:33:47
User entered 'No (N)'	System	01 Oct 2020 18:33:47

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-01T12:33:38', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '4ab60aa1-4969-45fa-af76-c1a8e69944c7'	System	01 Oct 2020 18:33:47
User entered 'No (N)'	System	01 Oct 2020 18:33:47

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:22:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-01T12:33:41', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '4ab60aa1-4969-45fa-af76-c1a8e69944c7'	System	01 Oct 2020 18:33:47
User entered 'None (1)'	System	01 Oct 2020 18:33:47

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-01T12:33:43', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '4ab60aa1-4969-45fa-af76-c1a8e69944c7'	System	01 Oct 2020 18:33:47
User entered '01 Oct 2020 12:33'	System	01 Oct 2020 18:33:47



**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 14:36:34

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 14:36:34

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	28 Sep 2020 14:36:34
User entered 'Day 5'	System	28 Sep 2020 14:36:34

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:22:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-03T06:35:50', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '91960bf1-285d-4fd2-ad6a-6338e6e3bccf'	System	03 Oct 2020 12:36:06
User entered 'None (1)'	System	03 Oct 2020 12:36:06

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:22:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-03T06:35:53', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '91960bf1-285d-4fd2-ad6a-6338e6e3bccf'	System	03 Oct 2020 12:36:06
User entered 'No (N)'	System	03 Oct 2020 12:36:06

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-03T06:35:55', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '91960bf1-285d-4fd2-ad6a-6338e6e3bccf'	System	03 Oct 2020 12:36:06
User entered 'No (N)'	System	03 Oct 2020 12:36:06

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:22:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-03T06:35:58', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '91960bf1-285d-4fd2-ad6a-6338e6e3bccf'	System	03 Oct 2020 12:36:06
User entered 'None (1)'	System	03 Oct 2020 12:36:06

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-03T06:36:01', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '91960bf1-285d-4fd2-ad6a-6338e6e3bccf'	System	03 Oct 2020 12:36:06
User entered '03 Oct 2020 06:36'	System	03 Oct 2020 12:36:06



**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 14:36:34

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 14:36:34

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	28 Sep 2020 14:36:34
User entered 'Day 6'	System	28 Sep 2020 14:36:34

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:22:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-03T22:41:51', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '57a9d1ab-be16-47fe-8fae-e6d1230b8245'	System	04 Oct 2020 04:42:07
User entered 'None (1)'	System	04 Oct 2020 04:42:07

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:22:50

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-03T22:41:54', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '57a9d1ab-be16-47fe-8fae-e6d1230b8245'	System	04 Oct 2020 04:42:07
User entered 'No (N)'	System	04 Oct 2020 04:42:07

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-03T22:41:56', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '57a9d1ab-be16-47fe-8fae-e6d1230b8245'	System	04 Oct 2020 04:42:07
User entered 'No (N)'	System	04 Oct 2020 04:42:07

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:22:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-03T22:41:58', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '57a9d1ab-be16-47fe-8fae-e6d1230b8245'	System	04 Oct 2020 04:42:07
User entered 'None (1)'	System	04 Oct 2020 04:42:07

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-03T22:42:01', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '57a9d1ab-be16-47fe-8fae-e6d1230b8245'	System	04 Oct 2020 04:42:07
User entered '03 Oct 2020 22:42'	System	04 Oct 2020 04:42:07



**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 14:36:34

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 14:36:34

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	28 Sep 2020 14:36:34
User entered 'Day 7'	System	28 Sep 2020 14:36:34

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:22:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-04T12:19:57', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '6f40b733-0ef8-4756-86b4-f9e17eaeabd9'	System	04 Oct 2020 18:20:11
User entered 'None (1)'	System	04 Oct 2020 18:20:11

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-04T12:20:00', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '6f40b733-0ef8-4756-86b4-f9e17eaeabd9'	System	04 Oct 2020 18:20:11
User entered 'No (N)'	System	04 Oct 2020 18:20:11

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-04T12:20:01', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '6f40b733-0ef8-4756-86b4-f9e17eaeabd9'	System	04 Oct 2020 18:20:11
User entered 'No (N)'	System	04 Oct 2020 18:20:11

US3892042

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:22:50

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-04T12:20:03', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '6f40b733-0ef8-4756-86b4-f9e17eaeabd9'	System	04 Oct 2020 18:20:11
User entered 'None (1)'	System	04 Oct 2020 18:20:11

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-04T12:20:06', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '6f40b733-0ef8-4756-86b4-f9e17eaeabd9'	System	04 Oct 2020 18:20:11
User entered '04 Oct 2020 12:20'	System	04 Oct 2020 18:20:11



**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 14:36:34

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 14:36:34

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	28 Sep 2020 14:36:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 14:36:34

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:22:50

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-28T08:49:38', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '6ec47fdf-c25c-40c4-abe0-a082b1fd80d7'	System	28 Sep 2020 14:49:57
User entered 'None (0)'	System	28 Sep 2020 14:49:57

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:22:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-28T08:49:40', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '6ec47fdf-c25c-40c4-abe0-a082b1fd80d7'	System	28 Sep 2020 14:49:57
User entered 'None (0)'	System	28 Sep 2020 14:49:57

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:22:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-28T08:49:43', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '6ec47fdf-c25c-40c4-abe0-a082b1fd80d7'	System	28 Sep 2020 14:49:57
User entered 'None (0)'	System	28 Sep 2020 14:49:57

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:22:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-28T08:49:45', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '6ec47fdf-c25c-40c4-abe0-a082b1fd80d7'	System	28 Sep 2020 14:49:57
User entered 'None (0)'	System	28 Sep 2020 14:49:57

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:22:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-28T08:49:47', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '6ec47fdf-c25c-40c4-abe0-a082b1fd80d7'	System	28 Sep 2020 14:49:57
User entered 'None (0)'	System	28 Sep 2020 14:49:57



**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:22:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-28T08:49:49', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '6ec47fdf-c25c-40c4-abe0-a082b1fd80d7'	System	28 Sep 2020 14:49:57
User entered 'None (0)'	System	28 Sep 2020 14:49:57

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-28T08:49:51', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '6ec47fdf-c25c-40c4-abe0-a082b1fd80d7'	System	28 Sep 2020 14:49:57
User entered 'No (N)'	System	28 Sep 2020 14:49:57

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-28T08:49:53', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '6ec47fdf-c25c-40c4-abe0-a082b1fd80d7'	System	28 Sep 2020 14:49:57
User entered '28 Sep 2020 08:49'	System	28 Sep 2020 14:49:57

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '28 Sep 2020 08:34'	System	28 Sep 2020 14:36:34

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '28 Sep 2020 11:04'	System	28 Sep 2020 14:36:34

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	28 Sep 2020 14:36:34
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 14:36:34

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:22:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-29T03:30:30', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'b2edb58f-1242-47ac-990b-4f30e1aa06d9'	System	29 Sep 2020 09:31:10
User entered 'No interference with activity (1)'	System	29 Sep 2020 09:31:10

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:22:50**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-29T03:30:36', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'b2edb58f-1242-47ac-990b-4f30e1aa06d9'	System	29 Sep 2020 09:31:10
User entered 'No interference with activity (1)'	System	29 Sep 2020 09:31:10



US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:22:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-29T03:30:42', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'b2edb58f-1242-47ac-990b-4f30e1aa06d9'	System	29 Sep 2020 09:31:10
User entered 'Some interference with activity (2)'	System	29 Sep 2020 09:31:10

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:22:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-29T03:30:48', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'b2edb58f-1242-47ac-990b-4f30e1aa06d9'	System	29 Sep 2020 09:31:10
User entered 'Some interference with activity (2)'	System	29 Sep 2020 09:31:10

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:22:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-29T03:30:51', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'b2edb58f-1242-47ac-990b-4f30e1aa06d9'	System	29 Sep 2020 09:31:10
User entered 'None (0)'	System	29 Sep 2020 09:31:10

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:22:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-29T03:30:59', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'b2edb58f-1242-47ac-990b-4f30e1aa06d9'	System	29 Sep 2020 09:31:10
User entered 'Some interference with activity not requiring medical attention (2)'	System	29 Sep 2020 09:31:10

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-29T03:31:04', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'b2edb58f-1242-47ac-990b-4f30e1aa06d9'	System	29 Sep 2020 09:31:10
User entered 'No (N)'	System	29 Sep 2020 09:31:10

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-29T03:31:07', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'b2edb58f-1242-47ac-990b-4f30e1aa06d9'	System	29 Sep 2020 09:31:10
User entered '29 Sep 2020 03:31'	System	29 Sep 2020 09:31:10

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '28 Sep 2020 11:59'	System	28 Sep 2020 14:36:34

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 14:36:34



US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	28 Sep 2020 14:36:34
User entered 'Day 2'	System	28 Sep 2020 14:36:34

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:22:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-29T15:26:54', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'c66d35c7-2acb-473e-9bf0-1d4258d59165'	System	29 Sep 2020 21:27:34
User entered 'No interference with activity (1)'	System	29 Sep 2020 21:27:34

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:22:50**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-29T15:27:05', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'c66d35c7-2acb-473e-9bf0-1d4258d59165'	System	29 Sep 2020 21:27:34
User entered 'Some interference with activity (2)'	System	29 Sep 2020 21:27:34

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:22:50**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-29T15:27:09', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'c66d35c7-2acb-473e-9bf0-1d4258d59165'	System	29 Sep 2020 21:27:34
User entered 'Some interference with activity (2)'	System	29 Sep 2020 21:27:34

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:22:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-29T15:27:12', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'c66d35c7-2acb-473e-9bf0-1d4258d59165'	System	29 Sep 2020 21:27:34
User entered 'Some interference with activity (2)'	System	29 Sep 2020 21:27:34

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:22:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-29T15:27:15', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'c66d35c7-2acb-473e-9bf0-1d4258d59165'	System	29 Sep 2020 21:27:34
User entered 'None (0)'	System	29 Sep 2020 21:27:34

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:22:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-29T15:27:20', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'c66d35c7-2acb-473e-9bf0-1d4258d59165'	System	29 Sep 2020 21:27:34
User entered 'No interference with activity (1)'	System	29 Sep 2020 21:27:34

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-29T15:27:26', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'c66d35c7-2acb-473e-9bf0-1d4258d59165'	System	29 Sep 2020 21:27:34
User entered 'No (N)'	System	29 Sep 2020 21:27:34



**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (543eb6727af7d043)', Time: '2020-09-29T15:27:28', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'c66d35c7-2acb-473e-9bf0-1d4258d59165'	System	29 Sep 2020 21:27:34
User entered '29 Sep 2020 15:27'	System	29 Sep 2020 21:27:34

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 14:36:34

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 14:36:34

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	28 Sep 2020 14:36:34
User entered 'Day 3'	System	28 Sep 2020 14:36:34

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:22:50

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-09-30T16:18:33', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'e59850ec-4258-4013-918d-18ed2e01a206'	System	30 Sep 2020 22:19:04
User entered 'No interference with activity (1)'	System	30 Sep 2020 22:19:04

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:22:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-09-30T16:18:40', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'e59850ec-4258-4013-918d-18ed2e01a206'	System	30 Sep 2020 22:19:04
User entered 'No interference with activity (1)'	System	30 Sep 2020 22:19:04

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:22:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-09-30T16:18:45', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'e59850ec-4258-4013-918d-18ed2e01a206'	System	30 Sep 2020 22:19:04
User entered 'Some interference with activity (2)'	System	30 Sep 2020 22:19:04

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:22:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-09-30T16:18:48', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'e59850ec-4258-4013-918d-18ed2e01a206'	System	30 Sep 2020 22:19:04
User entered 'Some interference with activity (2)'	System	30 Sep 2020 22:19:04



US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:22:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-09-30T16:18:50', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'e59850ec-4258-4013-918d-18ed2e01a206'	System	30 Sep 2020 22:19:04
User entered 'None (0)'	System	30 Sep 2020 22:19:04

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:22:50

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-09-30T16:18:54', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'e59850ec-4258-4013-918d-18ed2e01a206'	System	30 Sep 2020 22:19:04
User entered 'None (0)'	System	30 Sep 2020 22:19:04

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-09-30T16:18:57', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'e59850ec-4258-4013-918d-18ed2e01a206'	System	30 Sep 2020 22:19:04
User entered 'No (N)'	System	30 Sep 2020 22:19:04

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-09-30T16:18:59', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'e59850ec-4258-4013-918d-18ed2e01a206'	System	30 Sep 2020 22:19:04
User entered '30 Sep 2020 16:18'	System	30 Sep 2020 22:19:04

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 14:36:34

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 14:36:34

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	28 Sep 2020 14:36:34
User entered 'Day 4'	System	28 Sep 2020 14:36:34

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:22:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-01T12:33:46', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '05ddf9e3-8d96-4a70-8cd0-cfeac5392754'	System	01 Oct 2020 18:34:06
User entered 'None (0)'	System	01 Oct 2020 18:34:06



US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:22:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-01T12:33:49', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '05ddf9e3-8d96-4a70-8cd0-cfeac5392754'	System	01 Oct 2020 18:34:06
User entered 'No interference with activity (1)'	System	01 Oct 2020 18:34:06

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:22:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-01T12:33:51', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '05ddf9e3-8d96-4a70-8cd0-cfeac5392754'	System	01 Oct 2020 18:34:06
User entered 'None (0)'	System	01 Oct 2020 18:34:06

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:22:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-01T12:33:53', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '05ddf9e3-8d96-4a70-8cd0-cfeac5392754'	System	01 Oct 2020 18:34:06
User entered 'None (0)'	System	01 Oct 2020 18:34:06

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:22:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-01T12:33:55', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '05ddf9e3-8d96-4a70-8cd0-cfeac5392754'	System	01 Oct 2020 18:34:06
User entered 'None (0)'	System	01 Oct 2020 18:34:06

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:22:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-01T12:33:57', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '05ddf9e3-8d96-4a70-8cd0-cfeac5392754'	System	01 Oct 2020 18:34:06
User entered 'None (0)'	System	01 Oct 2020 18:34:06

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-01T12:33:59', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '05ddf9e3-8d96-4a70-8cd0-cfeac5392754'	System	01 Oct 2020 18:34:06
User entered 'No (N)'	System	01 Oct 2020 18:34:06

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-01T12:34:01', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '05ddf9e3-8d96-4a70-8cd0-cfeac5392754'	System	01 Oct 2020 18:34:06
User entered '01 Oct 2020 12:34'	System	01 Oct 2020 18:34:06

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 14:36:34



**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 14:36:34

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	28 Sep 2020 14:36:34
User entered 'Day 5'	System	28 Sep 2020 14:36:34

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 10:22:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-03T06:36:04', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '4c620889-0ea8-48de-bd5a-eec593bdf47a'	System	03 Oct 2020 12:36:27
User entered 'None (0)'	System	03 Oct 2020 12:36:27

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:22:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-03T06:36:06', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '4c620889-0ea8-48de-bd5a-eec593bdf47a'	System	03 Oct 2020 12:36:27
User entered 'None (0)'	System	03 Oct 2020 12:36:27

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:22:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-03T06:36:09', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '4c620889-0ea8-48de-bd5a-eec593bdf47a'	System	03 Oct 2020 12:36:27
User entered 'None (0)'	System	03 Oct 2020 12:36:27

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:22:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-03T06:36:10', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '4c620889-0ea8-48de-bd5a-eec593bdf47a'	System	03 Oct 2020 12:36:27
User entered 'None (0)'	System	03 Oct 2020 12:36:27

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:22:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-03T06:36:13', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '4c620889-0ea8-48de-bd5a-eec593bdf47a'	System	03 Oct 2020 12:36:27
User entered 'None (0)'	System	03 Oct 2020 12:36:27

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 10:22:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-03T06:36:16', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '4c620889-0ea8-48de-bd5a-eec593bdf47a'	System	03 Oct 2020 12:36:27
User entered 'None (0)'	System	03 Oct 2020 12:36:27



US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-03T06:36:18', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '4c620889-0ea8-48de-bd5a-eec593bdf47a'	System	03 Oct 2020 12:36:27
User entered 'No (N)'	System	03 Oct 2020 12:36:27

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-03T06:36:20', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '4c620889-0ea8-48de-bd5a-eec593bdf47a'	System	03 Oct 2020 12:36:27
User entered '03 Oct 2020 06:36'	System	03 Oct 2020 12:36:27

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 14:36:34

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 14:36:34

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:22:50

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	28 Sep 2020 14:36:34
User entered 'Day 6'	System	28 Sep 2020 14:36:34

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:22:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-03T22:42:04', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '7a44c648-d283-4f70-a082-e1be0c3cf961'	System	04 Oct 2020 04:42:25
User entered 'None (0)'	System	04 Oct 2020 04:42:25

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:22:50

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-03T22:42:06', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '7a44c648-d283-4f70-a082-e1be0c3cf961'	System	04 Oct 2020 04:42:25
User entered 'None (0)'	System	04 Oct 2020 04:42:25

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:22:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-03T22:42:08', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '7a44c648-d283-4f70-a082-e1be0c3cf961'	System	04 Oct 2020 04:42:25
User entered 'None (0)'	System	04 Oct 2020 04:42:25



US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:22:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-03T22:42:11', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '7a44c648-d283-4f70-a082-e1be0c3cf961'	System	04 Oct 2020 04:42:25
User entered 'None (0)'	System	04 Oct 2020 04:42:25

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:22:50

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-03T22:42:14', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '7a44c648-d283-4f70-a082-e1be0c3cf961'	System	04 Oct 2020 04:42:25
User entered 'None (0)'	System	04 Oct 2020 04:42:25

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:22:50

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-03T22:42:16', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '7a44c648-d283-4f70-a082-e1be0c3cf961'	System	04 Oct 2020 04:42:25
User entered 'None (0)'	System	04 Oct 2020 04:42:25

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-03T22:42:18', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '7a44c648-d283-4f70-a082-e1be0c3cf961'	System	04 Oct 2020 04:42:25
User entered 'No (N)'	System	04 Oct 2020 04:42:25

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-03T22:42:20', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '7a44c648-d283-4f70-a082-e1be0c3cf961'	System	04 Oct 2020 04:42:25
User entered '03 Oct 2020 22:42'	System	04 Oct 2020 04:42:25

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 14:36:34

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 14:36:34

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	28 Sep 2020 14:36:34
User entered 'Day 7'	System	28 Sep 2020 14:36:34



**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:22:50**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-04T12:20:09', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '2a704c72-ef28-4606-88cb-516ddf120cb3'	System	04 Oct 2020 18:20:24
User entered 'None (0)'	System	04 Oct 2020 18:20:24

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:22:50**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-04T12:20:10', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '2a704c72-ef28-4606-88cb-516ddf120cb3'	System	04 Oct 2020 18:20:24
User entered 'None (0)'	System	04 Oct 2020 18:20:24

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:22:50

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-04T12:20:12', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '2a704c72-ef28-4606-88cb-516ddf120cb3'	System	04 Oct 2020 18:20:24
User entered 'None (0)'	System	04 Oct 2020 18:20:24

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:22:50

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-04T12:20:14', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '2a704c72-ef28-4606-88cb-516ddf120cb3'	System	04 Oct 2020 18:20:24
User entered 'None (0)'	System	04 Oct 2020 18:20:24

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:22:50**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-04T12:20:15', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '2a704c72-ef28-4606-88cb-516ddf120cb3'	System	04 Oct 2020 18:20:24
User entered 'None (0)'	System	04 Oct 2020 18:20:24

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:22:50**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-04T12:20:17', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '2a704c72-ef28-4606-88cb-516ddf120cb3'	System	04 Oct 2020 18:20:24
User entered 'None (0)'	System	04 Oct 2020 18:20:24

US3892042

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-04T12:20:19', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '2a704c72-ef28-4606-88cb-516ddf120cb3'	System	04 Oct 2020 18:20:24
User entered 'No (N)'	System	04 Oct 2020 18:20:24

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-10-04T12:20:21', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '2a704c72-ef28-4606-88cb-516ddf120cb3'	System	04 Oct 2020 18:20:24
User entered '04 Oct 2020 12:20'	System	04 Oct 2020 18:20:24



**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 14:36:34

**US3892042**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:22:50**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 14:36:34

US3892042

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:47
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	(b) (4)	05 Oct 2020 15:01:32
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	05 Oct 2020 15:01:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 15:01:13

US3892042

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:50

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:47
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '5 Oct 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:01:32
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 15:01:13

**US3892042**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:22:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:47
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:01:13

US3892042

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:50

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:47
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:01:13

**US3892042**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:22:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:47
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Oct 2020 15:01:38

**US3892042**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:22:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:47
User entered 'I'	System	05 Oct 2020 15:01:38



**US3892042**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:22:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Yes (Y)'	(b) (4) chase Carnahan (b) (4)	12 Oct 2020 17:32:01

**US3892042**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:22:50**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '12 Oct 2020'	(b) (4) chase Carnahan (b) (4)	12 Oct 2020 17:32:01

**US3892042**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:22:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) chase Carnahan (b) (4)	12 Oct 2020 17:32:01

**US3892042**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:22:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered empty.	(b) (4) chase Carnahan (b) (4)	12 Oct 2020 17:32:01

**US3892042**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:22:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Yes (Y)'	(b) (4) chase Carnahan (b) (4)	12 Oct 2020 17:32:23

**US3892042**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:22:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered 'I'	System	12 Oct 2020 17:32:23

**US3892042**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:22:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:57:23

**US3892042**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:22:50**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '20 Oct 2020'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:57:23



**US3892042**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:22:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:57:23

US3892042

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:50

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:57:23

**US3892042**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:22:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Oct 2020 22:57:27

**US3892042**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:22:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered 'I'	System	20 Oct 2020 22:57:27

**US3892042**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:22:50**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	27 Oct 2020 14:49:01

**US3892042**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '27 Oct 2020'	(b) (4) Andryelle Toledo (b) (4)	27 Oct 2020 14:49:01

**US3892042**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Clinic (Clinic)'	(b) (4) Andryelle Toledo (b) (4)	27 Oct 2020 14:49:01

**US3892042**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:22:50**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered 'VISIT3'	System	27 Oct 2020 14:49:01



**US3892042**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	27 Oct 2020 14:49:28

**US3892042**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '27 Oct 2020'	(b) (4) Andryelle Toledo (b) (4)	27 Oct 2020 14:49:28

**US3892042**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '07:12'	(b) (4) Andryelle Toledo (b) (4)	27 Oct 2020 14:49:28

**US3892042**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered '27 Oct 2020 07:12'	System	27 Oct 2020 14:49:28

**US3892042**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '97.0' F	(b) (4) Andryelle Toledo (b) (4)	27 Oct 2020 14:49:28

**US3892042**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Oral (Oral)'	(b) (4) Andryelle Toledo (b) (4)	27 Oct 2020 14:49:28

**US3892042**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	27 Oct 2020 14:49:28

**US3892042**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '61'	(b) (4) Andryelle Toledo (b) (4)	27 Oct 2020 14:49:28



**US3892042**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered 'bpm'	System	27 Oct 2020 14:49:28

**US3892042**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '12'	(b) (4) Andryelle Toledo (b) (4)	27 Oct 2020 14:49:28

**US3892042**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered 'breaths/min'	System	27 Oct 2020 14:49:28

**US3892042**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '134'	(b) (4) Andryelle Toledo (b) (4)	27 Oct 2020 14:49:28

**US3892042**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered 'mmHg'	System	27 Oct 2020 14:49:28

**US3892042**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '78'	(b) (4) Andryelle Toledo (b) (4)	27 Oct 2020 14:49:28

**US3892042**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered 'mmHg'	System	27 Oct 2020 14:49:28

**US3892042**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55



**US3892042**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55

**US3892042**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 10:22:50**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	27 Oct 2020 14:49:37

**US3892042**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 10:22:50**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '27 Oct 2020'	(b) (4) Andryelle Toledo (b) (4)	27 Oct 2020 14:49:37

**US3892042**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:22:50**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	27 Oct 2020 14:49:50

US3892042

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:50

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '27 Oct 2020'	(b) (4) Andryelle Toledo (b) (4)	27 Oct 2020 14:49:50

**US3892042**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:22:50**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered '07:24'	(b) (4) Andryelle Toledo (b) (4)	27 Oct 2020 14:49:50

**US3892042**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:22:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered '27 Oct 2020 07:24'	System	27 Oct 2020 14:49:50

**US3892042**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:22:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	27 Oct 2020 14:49:55



**US3892042**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:22:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered 'I'	System	27 Oct 2020 14:49:55

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	01 Sep 2020 18:57:59
User entered 'Day 64'	System	01 Sep 2020 18:57:59

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-11-02T12:34:38', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '93d793f9-93c2-4f22-a532-5fc3c8076ffa'	System	02 Nov 2020 19:34:52
User entered 'No (N)'	System	02 Nov 2020 19:34:52

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-11-02T12:34:46', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '93d793f9-93c2-4f22-a532-5fc3c8076ffa'	System	02 Nov 2020 19:34:52
User entered 'No (N)'	System	02 Nov 2020 19:34:52

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-11-02T12:34:49', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '93d793f9-93c2-4f22-a532-5fc3c8076ffa'	System	02 Nov 2020 19:34:52
User entered '02 Nov 2020 12:34:49'	System	02 Nov 2020 19:34:52

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	01 Sep 2020 18:57:59
User entered '01 Nov 2020 00:01'	System	01 Sep 2020 18:57:59

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	01 Sep 2020 18:57:59
User entered '05 Nov 2020 23:59'	System	01 Sep 2020 18:57:59

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	01 Sep 2020 18:57:59
User entered 'Day 71'	System	01 Sep 2020 18:57:59



US3892042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-11-09T09:14:10', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '1285aab2-70ef-48bb-a274-a241d7bc328d'	System	09 Nov 2020 16:14:23
User entered 'No (N)'	System	09 Nov 2020 16:14:23

US3892042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-11-09T09:14:16', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '1285aab2-70ef-48bb-a274-a241d7bc328d'	System	09 Nov 2020 16:14:23
User entered 'No (N)'	System	09 Nov 2020 16:14:23

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-11-09T09:14:18', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '1285aab2-70ef-48bb-a274-a241d7bc328d'	System	09 Nov 2020 16:14:23
User entered '09 Nov 2020 09:14:18'	System	09 Nov 2020 16:14:23

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	01 Sep 2020 18:57:59
User entered '08 Nov 2020 00:01'	System	01 Sep 2020 18:57:59

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	01 Sep 2020 18:57:59
User entered '12 Nov 2020 23:59'	System	01 Sep 2020 18:57:59

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	01 Sep 2020 18:57:59
User entered 'Day 78'	System	01 Sep 2020 18:57:59

US3892042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-11-16T12:01:38', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '44c1d0e5-6a5c-45d3-9927-739ef9d15826'	System	16 Nov 2020 19:01:47
User entered 'No (N)'	System	16 Nov 2020 19:01:47

US3892042

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:22:50

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-11-16T12:01:41', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '44c1d0e5-6a5c-45d3-9927-739ef9d15826'	System	16 Nov 2020 19:01:47
User entered 'No (N)'	System	16 Nov 2020 19:01:47



**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-11-16T12:01:45', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '44c1d0e5-6a5c-45d3-9927-739ef9d15826'	System	16 Nov 2020 19:01:47
User entered '16 Nov 2020 12:01:45'	System	16 Nov 2020 19:01:47

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	01 Sep 2020 18:57:59
User entered '15 Nov 2020 00:01'	System	01 Sep 2020 18:57:59

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:22:26
Data entry locked.	System	01 Sep 2020 18:57:59
User entered '19 Nov 2020 23:59'	System	01 Sep 2020 18:57:59

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[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 (ea3324e87e2c3ef8)', Time: '2020-11-21T22:50:21', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '24526d48-991a-45a4-95e2-2378bc761055'	System	22 Nov 2020 05:51:12
User entered 'Yes (Y)'	System	22 Nov 2020 05:51:12

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

Have you been exposed to someone with 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 (ea3324e87e2c3ef8)', Time: '2020-11-21T22:50:25', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '24526d48-991a-45a4-95e2-2378bc761055'	System	22 Nov 2020 05:51:12
User entered 'No (N)'	System	22 Nov 2020 05:51:12

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[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 (ea3324e87e2c3ef8)', Time: '2020-11-21T22:50:31', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '24526d48-991a-45a4-95e2-2378bc761055'	System	22 Nov 2020 05:51:12
User entered 'Yes (Y)'	System	22 Nov 2020 05:51:12

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-11-21T22:50:38', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '24526d48-991a-45a4-95e2-2378bc761055'	System	22 Nov 2020 05:51:12
User entered '0'	System	22 Nov 2020 05:51:12



**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-11-21T22:50:38', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '24526d48-991a-45a4-95e2-2378bc761055'	System	22 Nov 2020 05:51:12
User entered '0'	System	22 Nov 2020 05:51:12

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-11-21T22:50:38', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '24526d48-991a-45a4-95e2-2378bc761055'	System	22 Nov 2020 05:51:12
User entered '1'	System	22 Nov 2020 05:51:12

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-11-21T22:50:38', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '24526d48-991a-45a4-95e2-2378bc761055'	System	22 Nov 2020 05:51:12
User entered '0'	System	22 Nov 2020 05:51:12

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-11-21T22:50:38', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '24526d48-991a-45a4-95e2-2378bc761055'	System	22 Nov 2020 05:51:12
User entered '0'	System	22 Nov 2020 05:51:12

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-11-21T22:50:38', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '24526d48-991a-45a4-95e2-2378bc761055'	System	22 Nov 2020 05:51:12
User entered '0'	System	22 Nov 2020 05:51:12

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-11-21T22:50:38', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '24526d48-991a-45a4-95e2-2378bc761055'	System	22 Nov 2020 05:51:12
User entered '0'	System	22 Nov 2020 05:51:12

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-11-21T22:50:38', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '24526d48-991a-45a4-95e2-2378bc761055'	System	22 Nov 2020 05:51:12
User entered '0'	System	22 Nov 2020 05:51:12

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-11-21T22:50:38', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '24526d48-991a-45a4-95e2-2378bc761055'	System	22 Nov 2020 05:51:12
User entered '0'	System	22 Nov 2020 05:51:12



**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-11-21T22:50:38', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '24526d48-991a-45a4-95e2-2378bc761055'	System	22 Nov 2020 05:51:12
User entered '0'	System	22 Nov 2020 05:51:12

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-11-21T22:50:38', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '24526d48-991a-45a4-95e2-2378bc761055'	System	22 Nov 2020 05:51:12
User entered '0'	System	22 Nov 2020 05:51:12

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-11-21T22:50:38', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '24526d48-991a-45a4-95e2-2378bc761055'	System	22 Nov 2020 05:51:12
User entered '1'	System	22 Nov 2020 05:51:12

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-11-21T22:50:38', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '24526d48-991a-45a4-95e2-2378bc761055'	System	22 Nov 2020 05:51:12
User entered '0'	System	22 Nov 2020 05:51:12

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-11-21T22:50:38', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '24526d48-991a-45a4-95e2-2378bc761055'	System	22 Nov 2020 05:51:12
User entered '0'	System	22 Nov 2020 05:51:12

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-11-21T22:50:38', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '24526d48-991a-45a4-95e2-2378bc761055'	System	22 Nov 2020 05:51:12
User entered '0'	System	22 Nov 2020 05:51:12

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-11-21T22:50:38', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '24526d48-991a-45a4-95e2-2378bc761055'	System	22 Nov 2020 05:51:12
User entered '0'	System	22 Nov 2020 05:51:12

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-11-21T22:50:38', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '24526d48-991a-45a4-95e2-2378bc761055'	System	22 Nov 2020 05:51:12
User entered '0'	System	22 Nov 2020 05:51:12



**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Please 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 (ea3324e87e2c3ef8)', Time: '2020-11-21T22:50:42', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '24526d48-991a-45a4-95e2-2378bc761055'	System	22 Nov 2020 05:51:12
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Nov 2020 05:51:12

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[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 (ea3324e87e2c3ef8)', Time: '2020-11-21T22:50:53', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '24526d48-991a-45a4-95e2-2378bc761055'	System	22 Nov 2020 05:51:12
User entered 'Yes (Y)'	System	22 Nov 2020 05:51:12

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Please 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 (ea3324e87e2c3ef8)', Time: '2020-11-21T22:50:58', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '24526d48-991a-45a4-95e2-2378bc761055'	System	22 Nov 2020 05:51:12
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Nov 2020 05:51:12

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-11-21T22:51:01', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '24526d48-991a-45a4-95e2-2378bc761055'	System	22 Nov 2020 05:51:12
User entered '21 Nov 2020 22:51:01'	System	22 Nov 2020 05:51:12

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[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 (ea3324e87e2c3ef8)', Time: '2020-11-30T09:57:52', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'c97e31a3-825d-4b41-a384-ddea7424aa28'	System	30 Nov 2020 16:58:01
User entered 'No (N)'	System	30 Nov 2020 16:58:01



**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

Have you been exposed to someone with 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 (ea3324e87e2c3ef8)', Time: '2020-11-30T09:57:56', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'c97e31a3-825d-4b41-a384-ddea7424aa28'	System	30 Nov 2020 16:58:01
User entered 'No (N)'	System	30 Nov 2020 16:58:01

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-11-30T09:57:58', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'c97e31a3-825d-4b41-a384-ddea7424aa28'	System	30 Nov 2020 16:58:01
User entered '30 Nov 2020 09:57:58'	System	30 Nov 2020 16:58:01

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[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 (ea3324e87e2c3ef8)', Time: '2020-12-03T05:24:20', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '18ecea63-4951-425b-b73d-72c994709dec'	System	03 Dec 2020 12:24:30
User entered 'No (N)'	System	03 Dec 2020 12:24:30

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

Have you been exposed to someone with 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 (ea3324e87e2c3ef8)', Time: '2020-12-03T05:24:25', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '18ecea63-4951-425b-b73d-72c994709dec'	System	03 Dec 2020 12:24:30
User entered 'No (N)'	System	03 Dec 2020 12:24:30

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-12-03T05:24:28', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '18ecea63-4951-425b-b73d-72c994709dec'	System	03 Dec 2020 12:24:30
User entered '03 Dec 2020 05:24:28'	System	03 Dec 2020 12:24:30



**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[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 (ea3324e87e2c3ef8)', Time: '2020-12-12T06:33:10', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '9d329464-a335-488f-b610-293252d5b1da'	System	12 Dec 2020 13:33:19
User entered 'No (N)'	System	12 Dec 2020 13:33:19

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Have you been exposed to someone with 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 (ea3324e87e2c3ef8)', Time: '2020-12-12T06:33:12', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '9d329464-a335-488f-b610-293252d5b1da'	System	12 Dec 2020 13:33:19
User entered 'No (N)'	System	12 Dec 2020 13:33:19

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-12-12T06:33:16', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '9d329464-a335-488f-b610-293252d5b1da'	System	12 Dec 2020 13:33:19
User entered '12 Dec 2020 06:33:16'	System	12 Dec 2020 13:33:19

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 21:46:57



**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[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 (ea3324e87e2c3ef8)', Time: '2020-12-17T08:37:49', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '2f55b75b-56eb-4f9e-a3be-7fa2d57430d0'	System	17 Dec 2020 15:38:00
User entered 'No (N)'	System	17 Dec 2020 15:38:00

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

Have you been exposed to someone with 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 (ea3324e87e2c3ef8)', Time: '2020-12-17T08:37:53', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '2f55b75b-56eb-4f9e-a3be-7fa2d57430d0'	System	17 Dec 2020 15:38:00
User entered 'No (N)'	System	17 Dec 2020 15:38:00

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-12-17T08:37:55', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '2f55b75b-56eb-4f9e-a3be-7fa2d57430d0'	System	17 Dec 2020 15:38:00
User entered '17 Dec 2020 08:37:55'	System	17 Dec 2020 15:38:00

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[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 (ea3324e87e2c3ef8)', Time: '2020-12-28T16:21:54', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '6df87859-1e14-4eca-a197-7b8ccd14939f'	System	28 Dec 2020 23:22:03
User entered 'No (N)'	System	28 Dec 2020 23:22:03



**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

Have you been exposed to someone with 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 (ea3324e87e2c3ef8)', Time: '2020-12-28T16:21:57', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '6df87859-1e14-4eca-a197-7b8ccd14939f'	System	28 Dec 2020 23:22:03
User entered 'No (N)'	System	28 Dec 2020 23:22:03

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-12-28T16:21:59', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '6df87859-1e14-4eca-a197-7b8ccd14939f' User entered '28 Dec 2020 16:21:59'	System	28 Dec 2020 23:22:03
	System	28 Dec 2020 23:22:03

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[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 (ea3324e87e2c3ef8)', Time: '2020-12-31T00:22:28', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '7d3fe823-98be-409c-9af1-113c6bc2c48b'	System	31 Dec 2020 07:22:36
User entered 'No (N)'	System	31 Dec 2020 07:22:36

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

Have you been exposed to someone with 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 (ea3324e87e2c3ef8)', Time: '2020-12-31T00:22:31', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '7d3fe823-98be-409c-9af1-113c6bc2c48b'	System	31 Dec 2020 07:22:36
User entered 'No (N)'	System	31 Dec 2020 07:22:36

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2020-12-31T00:22:33', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '7d3fe823-98be-409c-9af1-113c6bc2c48b'	System	31 Dec 2020 07:22:36
User entered '31 Dec 2020 00:22:33'	System	31 Dec 2020 07:22:36



**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[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 (ea3324e87e2c3ef8)', Time: '2021-01-11T08:34:05', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'ee0e72f1-6d22-4c2a-8650-5a436d2f6db0'	System	11 Jan 2021 15:34:18
User entered 'No (N)'	System	11 Jan 2021 15:34:18

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

Have you been exposed to someone with 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 (ea3324e87e2c3ef8)', Time: '2021-01-11T08:34:09', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'ee0e72f1-6d22-4c2a-8650-5a436d2f6db0'	System	11 Jan 2021 15:34:18
User entered 'No (N)'	System	11 Jan 2021 15:34:18

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2021-01-11T08:34:11', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'ee0e72f1-6d22-4c2a-8650-5a436d2f6db0'	System	11 Jan 2021 15:34:18
User entered '11 Jan 2021 08:34:11'	System	11 Jan 2021 15:34:18

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 21:46:57



**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[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 (ea3324e87e2c3ef8)', Time: '2021-01-18T14:13:09', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'cee5d36c-ed2d-4144-b081-fff7364140b8'	System	18 Jan 2021 21:13:19
User entered 'No (N)'	System	18 Jan 2021 21:13:19

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

Have you been exposed to someone with 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 (ea3324e87e2c3ef8)', Time: '2021-01-18T14:13:11', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'cee5d36c-ed2d-4144-b081-fff7364140b8'	System	18 Jan 2021 21:13:19
User entered 'No (N)'	System	18 Jan 2021 21:13:19

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2021-01-18T14:13:13', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'cee5d36c-ed2d-4144-b081-fff7364140b8' User entered '18 Jan 2021 14:13:13'	System	18 Jan 2021 21:13:19
	System	18 Jan 2021 21:13:19

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[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 (ea3324e87e2c3ef8)', Time: '2021-01-21T14:57:28', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'fadaf8a4-37ee-4128-b159-7929aded4a27'	System	21 Jan 2021 21:57:36
User entered 'No (N)'	System	21 Jan 2021 21:57:36



**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

Have you been exposed to someone with 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 (ea3324e87e2c3ef8)', Time: '2021-01-21T14:57:30', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'fadaf8a4-37ee-4128-b159-7929aded4a27'	System	21 Jan 2021 21:57:36
User entered 'No (N)'	System	21 Jan 2021 21:57:36

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2021-01-21T14:57:32', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'fadaf8a4-37ee-4128-b159-7929aded4a27'	System	21 Jan 2021 21:57:36
User entered '21 Jan 2021 14:57:32'	System	21 Jan 2021 21:57:36

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[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 (ea3324e87e2c3ef8)', Time: '2021-01-28T04:32:06', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '31d25446-7d34-45f5-8984-5564515c05cb'	System	28 Jan 2021 11:32:21
User entered 'No (N)'	System	28 Jan 2021 11:32:21

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

Have you been exposed to someone with 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 (ea3324e87e2c3ef8)', Time: '2021-01-28T04:32:14', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '31d25446-7d34-45f5-8984-5564515c05cb'	System	28 Jan 2021 11:32:21
User entered 'No (N)'	System	28 Jan 2021 11:32:21

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2021-01-28T04:32:16', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '31d25446-7d34-45f5-8984-5564515c05cb' User entered '28 Jan 2021 04:32:16'	System	28 Jan 2021 11:32:21



**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[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 (ea3324e87e2c3ef8)', Time: '2021-02-04T17:57:25', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '8de0da99-5abe-4552-91d1-81d36f1efbc7'	System	05 Feb 2021 00:57:34
User entered 'No (N)'	System	05 Feb 2021 00:57:34

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

Have you been exposed to someone with 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 (ea3324e87e2c3ef8)', Time: '2021-02-04T17:57:28', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '8de0da99-5abe-4552-91d1-81d36f1efbc7'	System	05 Feb 2021 00:57:34
User entered 'No (N)'	System	05 Feb 2021 00:57:34

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2021-02-04T17:57:30', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '8de0da99-5abe-4552-91d1-81d36f1efbc7'	System	05 Feb 2021 00:57:34
User entered '04 Feb 2021 17:57:30'	System	05 Feb 2021 00:57:34

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 21:46:57



**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[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 (ea3324e87e2c3ef8)', Time: '2021-02-11T00:51:03', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'c6e4c143-4adb-4b0c-a1ff-976064fa6c9a'	System	11 Feb 2021 07:51:13
User entered 'No (N)'	System	11 Feb 2021 07:51:13

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

Have you been exposed to someone with 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 (ea3324e87e2c3ef8)', Time: '2021-02-11T00:51:07', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'c6e4c143-4adb-4b0c-a1ff-976064fa6c9a'	System	11 Feb 2021 07:51:13
User entered 'No (N)'	System	11 Feb 2021 07:51:13

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2021-02-11T00:51:09', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'c6e4c143-4adb-4b0c-a1ff-976064fa6c9a' User entered '11 Feb 2021 00:51:09'	System	11 Feb 2021 07:51:13
	System	11 Feb 2021 07:51:13

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[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 (ea3324e87e2c3ef8)', Time: '2021-02-22T07:47:52', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'e4b6b40d-a1ab-43dd-a07e-128cd6399f4c'	System	22 Feb 2021 14:47:58
User entered 'No (N)'	System	22 Feb 2021 14:47:58



**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

Have you been exposed to someone with 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 (ea3324e87e2c3ef8)', Time: '2021-02-22T07:47:54', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'e4b6b40d-a1ab-43dd-a07e-128cd6399f4c'	System	22 Feb 2021 14:47:58
User entered 'No (N)'	System	22 Feb 2021 14:47:58

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2021-02-22T07:47:57', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'e4b6b40d-a1ab-43dd-a07e-128cd6399f4c'	System	22 Feb 2021 14:47:58
User entered '22 Feb 2021 07:47:57'	System	22 Feb 2021 14:47:58

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[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 (ea3324e87e2c3ef8)', Time: '2021-02-26T07:29:56-07:00', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'cf4921e1-6e5e-436e-9c32-035837e717ce'	System	26 Feb 2021 14:30:26
User entered 'Yes (Y)'	System	26 Feb 2021 14:30:26

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

Have you been exposed to someone with 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 (ea3324e87e2c3ef8)', Time: '2021-02-26T07:30:00-07:00', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'cf4921e1-6e5e-436e-9c32-035837e717ce'	System	26 Feb 2021 14:30:26
User entered 'No (N)'	System	26 Feb 2021 14:30:26

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[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 (ea3324e87e2c3ef8)', Time: '2021-02-26T07:30:04-07:00', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'cf4921e1-6e5e-436e-9c32-035837e717ce'	System	26 Feb 2021 14:30:26
User entered 'No (N)'	System	26 Feb 2021 14:30:26



**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[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 (ea3324e87e2c3ef8)', Time: '2021-02-26T07:30:20-07:00', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'cf4921e1-6e5e-436e-9c32-035837e717ce'	System	26 Feb 2021 14:30:26
User entered 'No (N)'	System	26 Feb 2021 14:30:26

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2021-02-26T07:30:23-07:00', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'cf4921e1-6e5e-436e-9c32-035837e717ce'	System	26 Feb 2021 14:30:26
User entered '26 Feb 2021 07:30:23'	System	26 Feb 2021 14:30:26

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[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 (ea3324e87e2c3ef8)', Time: '2021-03-04T00:47:22-07:00', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '1c4707c0-d044-4984-965a-e28d9aa4635a'	System	04 Mar 2021 07:47:37
User entered 'No (N)'	System	04 Mar 2021 07:47:37

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

Have you been exposed to someone with 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 (ea3324e87e2c3ef8)', Time: '2021-03-04T00:47:25-07:00', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '1c4707c0-d044-4984-965a-e28d9aa4635a'	System	04 Mar 2021 07:47:37
User entered 'No (N)'	System	04 Mar 2021 07:47:37

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2021-03-04T00:47:28-07:00', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '1c4707c0-d044-4984-965a-e28d9aa4635a' User entered '04 Mar 2021 00:47:28'	System	04 Mar 2021 07:47:37
	System	04 Mar 2021 07:47:37



**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[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 (ea3324e87e2c3ef8)', Time: '2021-03-12T11:23:57-07:00', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '91e3f310-0ccc-4c73-9fa2-e7b1060ac421'	System	12 Mar 2021 18:24:18
User entered 'No (N)'	System	12 Mar 2021 18:24:18

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

Have you been exposed to someone with 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 (ea3324e87e2c3ef8)', Time: '2021-03-12T11:24:02-07:00', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '91e3f310-0ccc-4c73-9fa2-e7b1060ac421'	System	12 Mar 2021 18:24:18
User entered 'No (N)'	System	12 Mar 2021 18:24:18

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2021-03-12T11:24:04-07:00', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '91e3f310-0ccc-4c73-9fa2-e7b1060ac421'	System	12 Mar 2021 18:24:18
User entered '12 Mar 2021 11:24:04'	System	12 Mar 2021 18:24:18

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 21:46:57



**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[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 (ea3324e87e2c3ef8)', Time: '2021-03-18T09:46:40-06:00', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '0a75b103-6964-4dd3-8b9f-cd2f09beae7b'	System	18 Mar 2021 15:46:48
User entered 'No (N)'	System	18 Mar 2021 15:46:48

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

Have you been exposed to someone with 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 (ea3324e87e2c3ef8)', Time: '2021-03-18T09:46:42-06:00', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '0a75b103-6964-4dd3-8b9f-cd2f09beae7b'	System	18 Mar 2021 15:46:48
User entered 'No (N)'	System	18 Mar 2021 15:46:48

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2021-03-18T09:46:44-06:00', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '0a75b103-6964-4dd3-8b9f-cd2f09beae7b' User entered '18 Mar 2021 09:46:44'	System	18 Mar 2021 15:46:48
	System	18 Mar 2021 15:46:48

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[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 (ea3324e87e2c3ef8)', Time: '2021-03-29T07:43:54-06:00', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '3643fabd-3c71-464e-8f95-94a60735d263'	System	29 Mar 2021 13:44:01
User entered 'No (N)'	System	29 Mar 2021 13:44:01



**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

Have you been exposed to someone with 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 (ea3324e87e2c3ef8)', Time: '2021-03-29T07:43:56-06:00', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '3643fabd-3c71-464e-8f95-94a60735d263'	System	29 Mar 2021 13:44:01
User entered 'No (N)'	System	29 Mar 2021 13:44:01

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2021-03-29T07:43:58-06:00', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '3643fabd-3c71-464e-8f95-94a60735d263' User entered '29 Mar 2021 07:43:58'	System	29 Mar 2021 13:44:01
	System	29 Mar 2021 13:44:01

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 21:46:57

**US3892042**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[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 (ea3324e87e2c3ef8)', Time: '2021-04-05T09:57:56-06:00', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'a79a988c-660b-4a06-8fae-29711c8acf43'	System	05 Apr 2021 15:58:10
User entered 'No (N)'	System	05 Apr 2021 15:58:10

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

Have you been exposed to someone with 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 (ea3324e87e2c3ef8)', Time: '2021-04-05T09:57:59-06:00', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'a79a988c-660b-4a06-8fae-29711c8acf43'	System	05 Apr 2021 15:58:10
User entered 'No (N)'	System	05 Apr 2021 15:58:10

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2021-04-05T09:58:01-06:00', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'a79a988c-660b-4a06-8fae-29711c8acf43'	System	05 Apr 2021 15:58:10
User entered '05 Apr 2021 09:58:01'	System	05 Apr 2021 15:58:10



**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[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 (ea3324e87e2c3ef8)', Time: '2021-04-09T10:54:22-06:00', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '9cf2126b-ab2d-4578-9258-c1bc7207843c' User entered 'No (N)'	System	09 Apr 2021 16:54:30
	System	09 Apr 2021 16:54:30

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

Have you been exposed to someone with 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 (ea3324e87e2c3ef8)', Time: '2021-04-09T10:54:24-06:00', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '9cf2126b-ab2d-4578-9258-c1bc7207843c'	System	09 Apr 2021 16:54:30
User entered 'No (N)'	System	09 Apr 2021 16:54:30

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2021-04-09T10:54:26-06:00', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '9cf2126b-ab2d-4578-9258-c1bc7207843c'	System	09 Apr 2021 16:54:30
User entered '09 Apr 2021 10:54:26'	System	09 Apr 2021 16:54:30

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 21:46:57



**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[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 (ea3324e87e2c3ef8)', Time: '2021-04-19T14:06:37-06:00', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'f2176a15-17a3-4848-a3c5-a03b66bcb665'	System	19 Apr 2021 20:06:47
User entered 'No (N)'	System	19 Apr 2021 20:06:47

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

Have you been exposed to someone with 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 (ea3324e87e2c3ef8)', Time: '2021-04-19T14:06:39-06:00', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'f2176a15-17a3-4848-a3c5-a03b66bcb665'	System	19 Apr 2021 20:06:47
User entered 'No (N)'	System	19 Apr 2021 20:06:47

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2021-04-19T14:06:41-06:00', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'f2176a15-17a3-4848-a3c5-a03b666bcb665'	System	19 Apr 2021 20:06:47
User entered '19 Apr 2021 14:06:41'	System	19 Apr 2021 20:06:47

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[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 (ea3324e87e2c3ef8)', Time: '2021-04-22T00:01:29-06:00', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'b728ea3b-65de-4040-a5eb-4d2260ebf9fa' User entered 'No (N)'	System	22 Apr 2021 06:01:37
	System	22 Apr 2021 06:01:37



**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

Have you been exposed to someone with 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 (ea3324e87e2c3ef8)', Time: '2021-04-22T00:01:31-06:00', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'b728ea3b-65de-4040-a5eb-4d2260ebf9fa' User entered 'No (N)'	System	22 Apr 2021 06:01:37

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2021-04-22T00:01:33-06:00', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'b728ea3b-65de-4040-a5eb-4d2260ebf9fa'	System	22 Apr 2021 06:01:37
User entered '22 Apr 2021 00:01:33'	System	22 Apr 2021 06:01:37

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[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 (ea3324e87e2c3ef8)', Time: '2021-04-29T00:06:57-06:00', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '835144ba-eeb5-4760-a789-a8ba143c53e0' User entered 'No (N)'	System	29 Apr 2021 06:07:07
	System	29 Apr 2021 06:07:07

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

Have you been exposed to someone with 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 (ea3324e87e2c3ef8)', Time: '2021-04-29T00:07:00-06:00', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '835144ba-eeb5-4760-a789-a8ba143c53e0' User entered 'No (N)'	System	29 Apr 2021 06:07:07
	System	29 Apr 2021 06:07:07

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2021-04-29T00:07:03-06:00', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: '835144ba-eeb5-4760-a789-a8ba143c53e0' User entered '29 Apr 2021 00:07:03'	System	29 Apr 2021 06:07:07
	System	29 Apr 2021 06:07:07



**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 21:46:57



**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 21:46:57



**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 21:46:57



**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 21:46:57



**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 21:46:57



**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 21:46:57



**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 21:46:57



**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 21:46:57



**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 21:46:57



**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 21:46:57



**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 21:46:57



**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 21:46:57



**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 21:46:57



**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 21:46:57



**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 21:46:57



**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 21:46:57



**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 21:46:57



**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 21:46:57



**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 21:46:57



**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 21:46:57



**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 21:46:57



**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 21:46:57



**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 21:46:57



**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 21:46:57



**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 21:46:57



**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 21:46:57



**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 21:46:57



**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 21:46:57



**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 21:46:57



**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '27 Oct 2022 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '31 Oct 2022 23:59'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '03 Nov 2022 00:01'	System	19 Nov 2020 21:46:57

**US3892042**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:22:50**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:46:57
Amendment Manager: User entered '07 Nov 2022 23:59'	System	19 Nov 2020 21:46:57

US3892042

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 10:22:50**

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)	25 Apr 2021 21:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2021-03-01T08:17:29-07:00', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'e21ce12a-82fc-41dd-944b-95a3f849bf09'	System	01 Mar 2021 15:18:00
User entered 'Yes (Y)'	System	01 Mar 2021 15:18:00



US3892042

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 10:22:50**

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2021-03-01T08:17:44-07:00', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'e21ce12a-82fc-41dd-944b-95a3f849bf09'	System	01 Mar 2021 15:18:00
User entered 'No (N)'	System	01 Mar 2021 15:18:00

**US3892042**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:08:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ea3324e87e2c3ef8)', Time: '2021-03-01T08:17:47-07:00', User OID: 'PatientReportedOutcome (US3892042)', ODM File OID: 'e21ce12a-82fc-41dd-944b-95a3f849bf09'	System	01 Mar 2021 15:18:00
User entered '01 Mar 2021 08:17:47'	System	01 Mar 2021 15:18:00

US3892042

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:50

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	(b) (4) System	04 Dec 2020 00:53:57
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	20 Nov 2020 00:40:56
User entered 'No (N)'	Andryelle Toledo (b) (4) (b) (4)	20 Nov 2020 00:40:56

US3892042

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:50

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	System	20 Nov 2020 00:41:47
answered by data change (Site from System).		
User entered empty; reason for change Data Entry Error	Andryelle Toledo (b) (4)	20 Nov 2020 00:41:47
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
User entered '19 Nov 2020' reason for change: Data Entry Error	System	20 Nov 2020 00:41:35
User entered empty.	Andryelle Toledo (b) (4)	20 Nov 2020 00:41:35
	(b) (4)	
	Andryelle Toledo (b) (4)	20 Nov 2020 00:40:56
	(b) (4)	

**US3892042**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:22:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered empty; reason for change Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	04 Dec 2020 00:53:57
	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT MADE)'	Andryelle Toledo (b) (4)	20 Nov 2020 00:40:56
	(b) (4)	

US3892042

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:22:50

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User closed query 'Kindly provide a comment on why contact not attempted. Thank you.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	08 Jan 2021 00:24:43
Query 'Kindly provide a comment on why contact not attempted. Thank you.' answered with 'update' (Site from CRA).	Andryelle Toledo (b) (4) (b) (4)	31 Dec 2020 01:24:42
User entered 'SUBJECT was IN CONVALESCENT PERIOD - ILLNESS VISIT' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	31 Dec 2020 01:24:34
User opened query 'Kindly provide a comment on why contact not attempted. Thank you.' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 20:55:35
User entered empty; reason for change Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	04 Dec 2020 00:53:57
User entered 'SUBJECT was IN CONVALESCENT PERIOD - ILLNESS VISIT.' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	20 Nov 2020 00:42:01
User entered 'Subject is in Convalescent Period - Illness visit.'	Andryelle Toledo (b) (4) (b) (4)	20 Nov 2020 00:40:56

**US3892042**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:22:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:26
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 00:41:04

**US3892042**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:22:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 06:01:55
User entered 'I'	System	20 Nov 2020 00:41:04



**US3892042**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:22:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:46:54
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Yes (Y)'	Courtney Jensen (b) (4)	28 Dec 2020 23:57:31

**US3892042**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:22:50**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:46:54
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '28 Dec 2020'	Courtney Jensen (b) (4)	28 Dec 2020 23:57:31

**US3892042**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:22:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:46:54
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Courtney Jensen (b) (4)	28 Dec 2020 23:57:31

**US3892042**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:22:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:46:54
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered empty.	Courtney Jensen (b) (4)	28 Dec 2020 23:57:31

**US3892042**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:22:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:46:54
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Yes (Y)'	(b) (4) Courtney Jensen (b) (4)	28 Dec 2020 23:57:35

**US3892042**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:22:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:46:54
User entered 'I'	System	28 Dec 2020 23:57:35

**US3892042**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:22:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:46:54
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	25 Jan 2021 15:45:38

**US3892042**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:22:50**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:46:54
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '25 Jan 2021'	(b) (4) Andryelle Toledo (b) (4)	25 Jan 2021 15:45:38



**US3892042**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:22:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:46:54
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Andryelle Toledo (b) (4)	25 Jan 2021 15:45:38

**US3892042**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:22:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:46:54
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	25 Jan 2021 15:45:38

**US3892042**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:22:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:46:54
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Yes (Y)'	(b) (4)	25 Jan 2021 15:46:03
	Andryelle Toledo (b) (4)	
	(b) (4)	

**US3892042**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:22:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:46:54
User entered 'I'	System	25 Jan 2021 15:46:03

**US3892042**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:22:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:46:54
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Yes (Y)'	Courtney Jensen (b) (4)	22 Feb 2021 20:13:01

**US3892042**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:22:50**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:46:54
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '22 Feb 2021'	Courtney Jensen (b) (4)	22 Feb 2021 20:13:01

**US3892042**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:22:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:46:54
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Courtney Jensen (b) (4)	22 Feb 2021 20:13:01

**US3892042**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:22:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:46:54
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered empty.	(b) (4) Courtney Jensen (b) (4)	22 Feb 2021 20:13:01



**US3892042**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:22:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:46:54
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Yes (Y)'	(b) (4) Courtney Jensen (b) (4)	22 Feb 2021 20:18:49

**US3892042**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:22:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:46:54
User entered 'I'	System	22 Feb 2021 20:18:49

**US3892042**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:22:50**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	30 Mar 2021 13:44:31
	(b) (4)	

**US3892042**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:22:50**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered '30 Mar 2021'	Andryelle Toledo (b) (4)	30 Mar 2021 13:44:31
	(b) (4)	

**US3892042**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:22:50**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered 'Clinic (Clinic)'	Andryelle Toledo (b) (4)	30 Mar 2021 13:44:31
	(b) (4)	

**US3892042**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:22:50**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	30 Mar 2021 13:44:31

**US3892042**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	30 Mar 2021 13:44:37
	(b) (4)	

**US3892042**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	30 Mar 2021 13:44:37
	(b) (4)	



**US3892042**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	30 Mar 2021 13:44:37
	(b) (4)	

**US3892042**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 13:44:37

**US3892042**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	30 Mar 2021 13:44:37
	(b) (4)	

**US3892042**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	30 Mar 2021 13:44:37
	(b) (4)	

**US3892042**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	30 Mar 2021 13:44:37
	(b) (4)	

**US3892042**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	30 Mar 2021 13:44:37
	(b) (4)	

**US3892042**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 13:44:37

US3892042

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	30 Mar 2021 13:44:37
	(b) (4)	



**US3892042**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 13:44:37

**US3892042**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	30 Mar 2021 13:44:37
	(b) (4)	

**US3892042**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 13:44:37

**US3892042**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	30 Mar 2021 13:44:37
	(b) (4)	

**US3892042**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Mar 2021 13:44:37

**US3892042**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 10:22:50**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	30 Mar 2021 13:44:43
	(b) (4)	

**US3892042**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 10:22:50**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered '30 Mar 2021'	Andryelle Toledo (b) (4)	30 Mar 2021 13:44:43
	(b) (4)	

**US3892042**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:22:50**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	30 Mar 2021 13:44:58
	(b) (4)	



**US3892042**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:22:50**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered '30 Mar 2021'	Andryelle Toledo (b) (4)	30 Mar 2021 13:44:58
	(b) (4)	

**US3892042**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:22:50**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered '07:32'	Andryelle Toledo (b) (4)	30 Mar 2021 13:44:58
	(b) (4)	

**US3892042**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:22:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '30 Mar 2021 07:32'	System	30 Mar 2021 13:44:58

**US3892042**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:22:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	30 Mar 2021 13:45:02
	(b) (4)	

**US3892042**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:22:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Mar 2021 13:45:02

**US3892042**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:22:50**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:40:20
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Apr 2021 18:35:16

**US3892042**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:22:50**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:40:20
	(b) (4)	
User entered '23 Apr 2021'	(b) (4), (b) (6)	23 Apr 2021 18:35:16

**US3892042**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:22:50**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:40:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:35:16



**US3892042**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:22:50**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:40:20
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 18:35:16

**US3892042**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:22:50**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:40:20
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Apr 2021 18:35:22

**US3892042**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:22:50**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Apr 2021 18:35:22

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 10:22:50**

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '19 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	20 Nov 2020 19:49:24
User entered '20 Nov 2020'	(b) (4)	
	Andryelle Toledo (b) (4)	20 Nov 2020 19:41:56
	(b) (4)	

US3892042

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:22:50

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Nov 2020 01:20:48
Query 'Data is required. Please complete.' answered with 'time is UNK' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 01:20:48
User opened query 'Data is required. Please complete.' (Site from System).	Andryelle Toledo (b) (4)	20 Nov 2020 19:49:30
User entered empty; reason for change Data Entry Error	(b) (4)	20 Nov 2020 19:49:24
User entered '08:55'	System	20 Nov 2020 19:49:24
	Andryelle Toledo (b) (4)	20 Nov 2020 19:49:24
	(b) (4)	20 Nov 2020 19:41:56
	Andryelle Toledo (b) (4)	20 Nov 2020 19:41:56
	(b) (4)	

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 10:22:50**

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:33
User entered empty.	System	20 Nov 2020 19:49:24
User entered '20 Nov 2020 08:55'	System	20 Nov 2020 19:41:56

US3892042

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:22:50

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Safety Call (Safety Call)' reason for change: Data Entry Error	(b) (4)	
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Andryelle Toledo (b) (4)	20 Nov 2020 19:49:24
	(b) (4)	
	Andryelle Toledo (b) (4)	20 Nov 2020 19:41:56
	(b) (4)	

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**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: COVID-19 Contact**

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[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:33
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	20 Nov 2020 19:41:56



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**Form: Symptom Log (1)**

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Day 1 (Day 1)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 19:43:42

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**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (1)**

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '18 Nov 2020'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 19:43:42

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (1)**

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 19:43:42

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:50

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Jan 2021 17:24:50
User entered empty.	Andryelle Toledo (b) (4)	20 Nov 2020 19:43:42
	(b) (4)	

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 10:22:50**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User entered '%'	System	21 Jan 2021 17:24:50
User entered empty.	System	20 Nov 2020 19:43:42

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Jan 2021 17:24:50
User entered empty.	Andryelle Toledo (b) (4)	20 Nov 2020 19:43:42
	(b) (4)	

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**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 19:43:42

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Mild (Mild)'	Andryelle Toledo (b) (4)	20 Nov 2020 19:43:42



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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 19:43:42

US3892042

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 10:22:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 19:43:42

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 19:43:42

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 19:43:42

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 19:43:42

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 19:43:42

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 10:22:50**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 19:43:42

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 10:22:50**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 19:43:42



**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 19:43:42

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 19:43:42

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 19:43:42

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 19:43:42

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**Folder: Covid-19 Assessment 19 Nov 2020**

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 19:43:42

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**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 19:43:42

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Day 2 (Day 2)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 20:09:48

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '19 Nov 2020'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 20:09:48



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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:50

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 20:09:48

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:50

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User closed query 'Per CDM: It appears that both O2 Saturation and Temperature were not collected for Days 1 and 2. If not collected, please consider recording these as Not Done. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 05:02:34
Query 'Per CDM: It appears that both O2 Saturation and Temperature were not collected for Days 1 and 2. If not collected, please consider recording these as Not Done. ' answered with 'update' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	21 Jan 2021 17:24:37
User entered missing code ND - Not Done; reason for change Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	21 Jan 2021 17:24:31
User opened query 'Per CDM: It appears that both O2 Saturation and Temperature were not collected for Days 1 and 2. If not collected, please consider recording these as Not Done. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 18:18:16
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	20 Nov 2020 20:09:48

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**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 10:22:50**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User entered '%'	System	21 Jan 2021 17:24:31
User entered empty.	System	20 Nov 2020 20:09:48

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:50

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	21 Jan 2021 17:24:31
User entered empty.	Andryelle Toledo (b) (4)	20 Nov 2020 20:09:48
	(b) (4)	

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**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 20:09:48

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**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 20:09:48

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 20:09:48

US3892042

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 20:09:48



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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 20:09:48

US3892042

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 10:22:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 20:09:48

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 20:09:48

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 20:09:48

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 10:22:50**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 20:09:48

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (2)**

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 20:09:48

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 20:09:48

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 20:09:48



**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 20:09:48

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 20:09:48

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 20:09:48

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 20:09:48

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Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Day 3 (Day 3)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 21:08:42

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '20 Nov 2020'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 21:08:42

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 21:08:42

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 10:22:50**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '95'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 21:08:42



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**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 10:22:50**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User entered '%'	System	20 Nov 2020 21:08:42

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '95.8' F	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 21:08:42

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 21:08:42

US3892042

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:50

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 21:08:42

US3892042

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:50

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 21:08:42

US3892042

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 21:08:42

US3892042

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 10:22:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 21:08:42

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 21:08:42



**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 21:08:42

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 21:08:42

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 10:22:50**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 21:08:42

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 10:22:50**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 21:08:42

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 21:08:42

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 21:08:42

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 21:08:42

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 21:08:42



**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 21:08:42

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Mild (Mild)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 21:08:42

US3892042

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 10:22:50

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Day 4 (Day 4)'	(b) (4) Leslie Iverson (b) (4)	23 Nov 2020 00:52:23

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 10:22:50**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '21 Nov 2020'	(b) (4) Leslie Iverson (b) (4)	23 Nov 2020 00:52:23

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 10:22:50**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '0'	Leslie Iverson (b) (4)	23 Nov 2020 00:52:23

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 10:22:50**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '97'	Leslie Iverson (b) (4)	23 Nov 2020 00:52:23

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 10:22:50**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User entered '%'	System	23 Nov 2020 00:52:23

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 10:22:50**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '95.8' F	Leslie Iverson (b) (4)	23 Nov 2020 00:52:23



**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 10:22:50**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	Leslie Iverson (b) (4)	23 Nov 2020 00:52:23

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 10:22:50**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Mild (Mild)'	Leslie Iverson (b) (4)	23 Nov 2020 00:52:23

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 10:22:50**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Leslie Iverson (b) (4)	23 Nov 2020 00:52:23

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 10:22:50**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	Leslie Iverson (b) (4)	23 Nov 2020 00:52:23

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 10:22:50**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	Leslie Iverson (b) (4)	23 Nov 2020 00:52:23

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 10:22:50**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Leslie Iverson (b) (4)	23 Nov 2020 00:52:23

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 10:22:50**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	Leslie Iverson (b) (4)	23 Nov 2020 00:52:23

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 10:22:50**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	Leslie Iverson (b) (4)	23 Nov 2020 00:52:23



**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 10:22:50**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Leslie Iverson (b) (4)	23 Nov 2020 00:52:23

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 10:22:50**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Leslie Iverson (b) (4)	23 Nov 2020 00:52:23

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 10:22:50**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Leslie Iverson (b) (4)	23 Nov 2020 00:52:23

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 10:22:50**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Leslie Iverson (b) (4)	23 Nov 2020 00:52:23

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 10:22:50**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Leslie Iverson (b) (4)	23 Nov 2020 00:52:23

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 10:22:50**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Leslie Iverson (b) (4)	23 Nov 2020 00:52:23

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 10:22:50**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	Leslie Iverson (b) (4)	23 Nov 2020 00:52:23

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (4)**

**Generated On: 10 Jun 2021 10:22:50**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Mild (Mild)'	Leslie Iverson (b) (4)	23 Nov 2020 00:52:23



**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 10:22:50**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Day 5 (Day 5)'	Leslie Iverson (b) (4)	23 Nov 2020 01:01:02

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 10:22:50**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '22 Nov 2020'	Leslie Iverson (b) (4)	23 Nov 2020 01:01:02

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 10:22:50**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '0'	Leslie Iverson (b) (4)	23 Nov 2020 01:01:02

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 10:22:50**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '96'	Leslie Iverson (b) (4)	23 Nov 2020 01:01:02

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 10:22:50**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User entered '%'	System	23 Nov 2020 01:01:02

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 10:22:50**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '96.0' F	Leslie Iverson (b) (4)	23 Nov 2020 01:01:02

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 10:22:50**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	Leslie Iverson (b) (4)	23 Nov 2020 01:01:02

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 10:22:50**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Mild (Mild)'	Leslie Iverson (b) (4)	23 Nov 2020 01:01:02



**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 10:22:50**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	Leslie Iverson (b) (4)	23 Nov 2020 01:01:02

US3892042

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Leslie Iverson (b) (4)	23 Nov 2020 01:01:02

US3892042

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 10:22:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Leslie Iverson (b) (4)	23 Nov 2020 01:01:02

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 10:22:50**

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Leslie Iverson (b) (4)	23 Nov 2020 01:01:02

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 10:22:50**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	Leslie Iverson (b) (4)	23 Nov 2020 01:01:02

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 10:22:50**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	Leslie Iverson (b) (4)	23 Nov 2020 01:01:02

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 10:22:50**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Leslie Iverson (b) (4)	23 Nov 2020 01:01:02

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 10:22:50**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Leslie Iverson (b) (4)	23 Nov 2020 01:01:02



**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 10:22:50**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Mild (Mild)'	Leslie Iverson (b) (4)	23 Nov 2020 01:01:02

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 10:22:50**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	Leslie Iverson (b) (4)	23 Nov 2020 01:01:02

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 10:22:50**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	Leslie Iverson (b) (4)	23 Nov 2020 01:01:02

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 10:22:50**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	Leslie Iverson (b) (4)	23 Nov 2020 01:01:02

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 10:22:50**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	Leslie Iverson (b) (4)	23 Nov 2020 01:01:02

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 10 Jun 2021 10:22:50**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Mild (Mild)'	Leslie Iverson (b) (4)	23 Nov 2020 01:01:02

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 10:22:50**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Day 6 (Day 6)'	Leslie Iverson (b) (4)	24 Nov 2020 23:44:52

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 10:22:50**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '23 Nov 2020'	Leslie Iverson (b) (4)	24 Nov 2020 23:44:52



**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 10:22:50**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '0'	Leslie Iverson (b) (4)	24 Nov 2020 23:44:52

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 10:22:50**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '97'	Leslie Iverson (b) (4)	24 Nov 2020 23:44:52

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 10:22:50**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User entered '%'	System	24 Nov 2020 23:44:52

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 10:22:50**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '95.8' F	(b) (4) Leslie Iverson (b) (4)	24 Nov 2020 23:44:52

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 10:22:50**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	Leslie Iverson (b) (4)	24 Nov 2020 23:44:52

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 10:22:50**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Mild (Mild)'	Leslie Iverson (b) (4)	24 Nov 2020 23:44:52

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 10:22:50**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	Leslie Iverson (b) (4)	24 Nov 2020 23:44:52

US3892042

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:50

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Leslie Iverson (b) (4)	24 Nov 2020 23:44:52



**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 10:22:50**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	Leslie Iverson (b) (4)	24 Nov 2020 23:44:52

US3892042

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Leslie Iverson (b) (4)	24 Nov 2020 23:44:52

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 10:22:50**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	Leslie Iverson (b) (4)	24 Nov 2020 23:44:52

US3892042

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 10:22:50

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	Leslie Iverson (b) (4)	24 Nov 2020 23:44:52

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 10:22:50**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Leslie Iverson (b) (4)	24 Nov 2020 23:44:52

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 10:22:50**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	Leslie Iverson (b) (4)	24 Nov 2020 23:44:52

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 10:22:50**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Mild (Mild)'	Leslie Iverson (b) (4)	24 Nov 2020 23:44:52

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 10:22:50**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	Leslie Iverson (b) (4)	24 Nov 2020 23:44:52



**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 10:22:50**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Leslie Iverson (b) (4)	24 Nov 2020 23:44:52

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 10:22:50**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	Leslie Iverson (b) (4)	24 Nov 2020 23:44:52

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 10:22:50**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	Leslie Iverson (b) (4)	24 Nov 2020 23:44:52

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 10 Jun 2021 10:22:50**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Mild (Mild)'	(b) (4) Leslie Iverson (b) (4)	24 Nov 2020 23:44:52

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 10:22:50**

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Day 7 (Day 7)'	(b) (4) Leslie Iverson (b) (4)	24 Nov 2020 23:46:21

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 10:22:50**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '24 Nov 2020'	Leslie Iverson (b) (4)	24 Nov 2020 23:46:21

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 10:22:50**

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '0'	Leslie Iverson (b) (4)	24 Nov 2020 23:46:21

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 10:22:50**

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '97'	Leslie Iverson (b) (4)	24 Nov 2020 23:46:21



**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 10:22:50**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User entered '%'	System	24 Nov 2020 23:46:21

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 10:22:50**

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '96.2' F	Leslie Iverson (b) (4)	24 Nov 2020 23:46:21

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 10:22:50**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	Leslie Iverson (b) (4)	24 Nov 2020 23:46:21

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 10:22:50**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Mild (Mild)'	Leslie Iverson (b) (4)	24 Nov 2020 23:46:21

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 10:22:50**

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Leslie Iverson (b) (4)	24 Nov 2020 23:46:21

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 10:22:50**

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Leslie Iverson (b) (4)	24 Nov 2020 23:46:21

US3892042

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:50

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	Leslie Iverson (b) (4)	24 Nov 2020 23:46:21

US3892042

Folder: Covid-19 Assessment 19 Nov 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 10:22:50

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	Leslie Iverson (b) (4)	24 Nov 2020 23:46:21



**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 10:22:50**

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	Leslie Iverson (b) (4)	24 Nov 2020 23:46:21

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 10:22:50**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	Leslie Iverson (b) (4)	24 Nov 2020 23:46:21

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 10:22:50**

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Leslie Iverson (b) (4)	24 Nov 2020 23:46:21

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 10:22:50**

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Leslie Iverson (b) (4)	24 Nov 2020 23:46:21

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 10:22:50**

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	(b) (4) Leslie Iverson (b) (4)	24 Nov 2020 23:46:21

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 10:22:50**

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	Leslie Iverson (b) (4)	24 Nov 2020 23:46:21

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 10:22:50**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	Leslie Iverson (b) (4)	24 Nov 2020 23:46:21

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 10:22:50**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	Leslie Iverson (b) (4)	24 Nov 2020 23:46:21



**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 10:22:50**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'None (None)'	Leslie Iverson (b) (4)	24 Nov 2020 23:46:21

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 10 Jun 2021 10:22:50**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:49
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Mild (Mild)'	(b) (4) Leslie Iverson (b) (4)	24 Nov 2020 23:46:21

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 10:22:50**

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '20 Nov 2020'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 19:44:10

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 10:22:50**

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	20 Nov 2020 19:44:10

US3892042

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:22:50

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 00:49:19
User entered 'No (N)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	04 Dec 2020 00:49:19
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	20 Nov 2020 19:44:10
	Andryelle Toledo (b) (4)	20 Nov 2020 19:44:10
	(b) (4)	

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 10:22:50**

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '20 Nov 2020'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 19:44:10

US3892042

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:22:50

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 19:44:10

US3892042

Folder: Covid-19 Assessment 19 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 10:22:50

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 19:44:10



**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 10:22:50**

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'No (N)'	Andryelle Toledo (b) (4)	20 Nov 2020 19:44:10

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 10:22:50**

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 19:44:10

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 10:22:50**

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 19:44:10

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 10 Jun 2021 10:22:50**

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:56:58
User entered '0'	System	04 Dec 2020 00:49:19

**US3892042**

**Folder: Covid-19 Assessment 19 Nov 2020**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 10 Jun 2021 10:22:50**

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:57:06
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 19:42:03

**US3892042**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:19:09
User accepted default value 'Day 3 (Day 3)'	Andryelle Toledo (b) (4)	31 Dec 2020 01:22:56
	(b) (4)	

**US3892042**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:19:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	31 Dec 2020 01:22:56

**US3892042**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:19:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '22 Nov 2020'	Andryelle Toledo (b) (4)	31 Dec 2020 01:22:56



**US3892042**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:19:09
User accepted default value 'Day 5 (Day 5)'	Andryelle Toledo (b) (4)	31 Dec 2020 01:22:56
	(b) (4)	

**US3892042**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:19:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	31 Dec 2020 01:22:56

**US3892042**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:19:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '24 Nov 2020'	Andryelle Toledo (b) (4)	31 Dec 2020 01:22:56

**US3892042**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:19:09
User accepted default value 'Day 7 (Day 7)'	Andryelle Toledo (b) (4)	31 Dec 2020 01:22:56
	(b) (4)	

**US3892042**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:19:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'NA (COVID-19 Negative) (NA)'	Andryelle Toledo (b) (4)	31 Dec 2020 01:22:56

**US3892042**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:19:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	31 Dec 2020 01:22:56

**US3892042**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 10:22:50**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:19:09
User accepted default value 'Day 9 (Day 9)'	Andryelle Toledo (b) (4)	31 Dec 2020 01:22:56
	(b) (4)	

**US3892042**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 10:22:50**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:19:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'NA (COVID-19 Negative) (NA)'	Andryelle Toledo (b) (4)	31 Dec 2020 01:22:56



**US3892042**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 10 Jun 2021 10:22:50**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:19:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	31 Dec 2020 01:22:56

**US3892042**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 10:22:50**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:19:09
User accepted default value 'Day 14 (Day 14)'	Andryelle Toledo (b) (4)	31 Dec 2020 01:22:56
	(b) (4)	

**US3892042**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 10:22:50**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:19:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'NA (COVID-19 Negative) (NA)'	Andryelle Toledo (b) (4)	31 Dec 2020 01:22:56

**US3892042**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 10 Jun 2021 10:22:50**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:19:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered empty.	Andryelle Toledo (b) (4)	31 Dec 2020 01:22:56

**US3892042**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 10:22:50**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:19:09
User accepted default value 'Day 21 (Day 21)'	Andryelle Toledo (b) (4)	31 Dec 2020 01:22:56
	(b) (4)	

**US3892042**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 10:22:50**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:19:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'NA (COVID-19 Negative) (NA)'	Andryelle Toledo (b) (4)	31 Dec 2020 01:22:56

**US3892042**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 10 Jun 2021 10:22:50**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:19:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered empty.	Andryelle Toledo (b) (4)	31 Dec 2020 01:22:56

**US3892042**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 10:22:50**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:19:09
User accepted default value 'Day 28 (Day 28)'	Andryelle Toledo (b) (4)	31 Dec 2020 01:22:56
	(b) (4)	



**US3892042**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 10:22:50**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:19:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'NA (COVID-19 Negative) (NA)'	Andryelle Toledo (b) (4)	31 Dec 2020 01:22:56

**US3892042**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 10 Jun 2021 10:22:50**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:19:09
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	31 Dec 2020 01:22:56

**US3892042**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:22:50**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:18:28
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	20 Nov 2020 16:57:09

US3892042

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:22:50

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:18:28
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 22NOV2020 and 24NOV2020 is reported under Illness visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Dec 2020 09:57:59
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 22NOV2020 and 24NOV2020 is reported under Illness visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you' answered with 'update' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	31 Dec 2020 01:25:06
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 22NOV2020 and 24NOV2020 is reported under Illness visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 04:50:48
User entered '20 Nov 2020'	Andryelle Toledo (b) (4) (b) (4)	20 Nov 2020 16:57:09

**US3892042**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:22:50**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:18:28
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Clinic (Clinic)'	Andryelle Toledo (b) (4)	20 Nov 2020 16:57:09

**US3892042**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:22:50**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:18:28
User entered 'SICKD1'	System	20 Nov 2020 16:57:09

**US3892042**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:18:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	20 Nov 2020 19:38:38

**US3892042**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:18:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '20 Nov 2020'	Andryelle Toledo (b) (4)	20 Nov 2020 19:38:38



**US3892042**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:18:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '09:00'	Andryelle Toledo (b) (4)	20 Nov 2020 19:38:38

**US3892042**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:18:35
User entered '20 Nov 2020 09:00'	System	20 Nov 2020 19:38:38

**US3892042**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:18:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered missing code ND - Not Done.	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 19:38:38
DataPoint set to visible.	(b) (4) System	20 Nov 2020 16:57:09

**US3892042**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:18:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered missing code ND - Not Done.	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 19:38:38
DataPoint set to visible.	(b) (4) System	20 Nov 2020 16:57:09

US3892042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:50

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:18:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 11:55:30
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Per PA: NCS' (Site from System).	Andryelle Toledo (b) (4) (b) (4)	04 Dec 2020 00:52:54
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	20 Nov 2020 19:38:38
User entered '95.8' F	Andryelle Toledo (b) (4) (b) (4)	20 Nov 2020 19:38:38

**US3892042**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:18:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Oral (Oral)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 19:38:38

**US3892042**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:18:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 19:38:38

**US3892042**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:18:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '65'	Andryelle Toledo (b) (4)	20 Nov 2020 19:38:38



**US3892042**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:18:35
User entered 'bpm'	System	20 Nov 2020 19:38:38

**US3892042**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:18:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '14'	Andryelle Toledo (b) (4)	20 Nov 2020 19:38:38

**US3892042**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:18:35
User entered 'breaths/min'	System	20 Nov 2020 19:38:38

**US3892042**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:18:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '140'	Andryelle Toledo (b) (4)	20 Nov 2020 19:38:38

**US3892042**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:18:35
User entered 'mmHg'	System	20 Nov 2020 19:38:38

US3892042

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:50

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:18:35
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User closed query 'Per CDM: Per CCG V2.0 page 53, Diastolic Blood Pressure $\geq$ 91 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:50:16
Query 'Per CDM: Per CCG V2.0 page 53, Diastolic Blood Pressure $\geq$ 91 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' answered with 'Per PA: NCS' (Site from DM).	Andryelle Toledo (b) (4) (b) (4)	04 Dec 2020 00:53:23
User opened query 'Per CDM: Per CCG V2.0 page 53, Diastolic Blood Pressure $\geq$ 91 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	29 Nov 2020 16:15:49
User entered '92'	Andryelle Toledo (b) (4) (b) (4)	20 Nov 2020 19:38:38

**US3892042**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:18:35
User entered 'mmHg'	System	20 Nov 2020 19:38:38

**US3892042**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:18:35



**US3892042**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:18:35

**US3892042**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 10:22:50**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:18:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	20 Nov 2020 19:40:40

**US3892042**

**Folder: Illness Visit Day 1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 10:22:50**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:18:40
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '20 Nov 2020'	Andryelle Toledo (b) (4)	20 Nov 2020 19:40:40

**US3892042**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 10 Jun 2021 10:22:50**

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:18:44
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Yes (Y)'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 19:41:01

**US3892042**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 10 Jun 2021 10:22:50**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:18:44
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '20 Nov 2020'	(b) (4) Andryelle Toledo (b) (4)	20 Nov 2020 19:41:01

**US3892042**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:22:50**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	31 Dec 2020 01:23:05
	(b) (4)	

**US3892042**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:22:50**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	31 Dec 2020 01:23:05
	(b) (4)	

**US3892042**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:22:50**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	31 Dec 2020 01:23:05
	(b) (4)	



**US3892042**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:22:50**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	31 Dec 2020 01:23:05

**US3892042**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	31 Dec 2020 01:23:11
	(b) (4)	

US3892042

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:50

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	31 Dec 2020 01:23:11
	(b) (4)	

**US3892042**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	31 Dec 2020 01:23:11
	(b) (4)	

**US3892042**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Dec 2020 01:23:11

US3892042

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:50

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	31 Dec 2020 01:23:11
	(b) (4)	

**US3892042**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	31 Dec 2020 01:23:11
	(b) (4)	

**US3892042**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	31 Dec 2020 01:23:11
	(b) (4)	



**US3892042**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	31 Dec 2020 01:23:11
	(b) (4)	

**US3892042**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Dec 2020 01:23:11

US3892042

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:22:50

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	31 Dec 2020 01:23:11
	(b) (4)	

**US3892042**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Dec 2020 01:23:11

**US3892042**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	31 Dec 2020 01:23:11
	(b) (4)	

**US3892042**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Dec 2020 01:23:11

**US3892042**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	31 Dec 2020 01:23:11
	(b) (4)	

**US3892042**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:22:50**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Dec 2020 01:23:11



**US3892042**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 10:22:50**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	31 Dec 2020 01:23:20
	(b) (4)	

US3892042

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:22:50

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	31 Dec 2020 01:23:20
	(b) (4)	

US3892042

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 10 Jun 2021 10:22:50**

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'NA (COVID-19 Negative) (NA)'	Andryelle Toledo (b) (4)	31 Dec 2020 01:23:24

**US3892042**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 10 Jun 2021 10:22:50**

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	31 Dec 2020 01:23:24
	(b) (4)	

**US3892042**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:22:50**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Jan 2021 17:18:40

**US3892042**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:22:50**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered '26 Jan 2021'	(b) (4), (b) (6)	26 Jan 2021 17:18:40

**US3892042**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:22:50**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	26 Jan 2021 17:18:40

**US3892042**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:22:50**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User entered 'UNBLND_DECIDE'	System	26 Jan 2021 17:18:40



**US3892042**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 10:22:50**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered '26 Jan 2021'	(b) (4), (b) (6)	28 Jan 2021 20:54:05

**US3892042**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 10:22:50**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:14:09

**US3892042**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 10:22:50**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	28 Jan 2021 20:54:05

**US3892042**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 10:22:50**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered 'AMENDMENT 5 (AMENDMENT 5)'	System	10 Mar 2021 16:55:28
WR# 5295537		
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:14:09

US3892042

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:22:50

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	(b) (4), (b) (6)	01 Feb 2021 12:57:13
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered with 'Date of unblinding and date of signed updated ICF are correct. Subject had priority status for EUA COVID-19 vaccination the week of 21Dec2020. Subject was unblinded to allow decision as to whether or not the subject needed to receive the vaccination through EUA or if the subject was already vaccinated during the trial.' (Site from System).	(b) (4), (b) (6)	28 Jan 2021 21:04:06
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	28 Jan 2021 20:54:05
User entered '21 Dec 2020'	(b) (4), (b) (6)	28 Jan 2021 20:54:05

US3892042

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:22:50

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	28 Jan 2021 20:54:05

**US3892042**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 10:22:50**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	28 Jan 2021 20:54:05

**US3892042**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 10:22:50**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6)	28 Jan 2021 20:54:05



US3892042

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:22:50

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	28 Jan 2021 20:54:05

**US3892042**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 10:22:50**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User entered empty.	System	28 Jan 2021 20:54:05

**US3892042**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 10:22:50**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User entered empty.	System	28 Jan 2021 20:54:05

US3892042

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:22:50

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Jan 2021 17:19:09

**US3892042**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:22:50**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered '26 Jan 2021'	(b) (4), (b) (6)	26 Jan 2021 17:19:09

**US3892042**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:22:50**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered '09:59'	(b) (4), (b) (6)	26 Jan 2021 17:19:09

**US3892042**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:22:50**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User entered '26 Jan 2021 09:59'	System	26 Jan 2021 17:19:09

**US3892042**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 10:22:50**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Jan 2021 17:19:23



**US3892042**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 10:22:50**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered '26 Jan 2021'	(b) (4), (b) (6)	26 Jan 2021 17:19:23

**US3892042**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 10:22:50**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered '10:08'	(b) (4), (b) (6)	26 Jan 2021 17:19:23

**US3892042**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 10:22:50**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:01:48
User entered '26 Jan 2021 10:08'	System	26 Jan 2021 17:19:23

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 10 Jun 2021 10:22:50**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:54:31
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:27
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	19 Nov 2020 22:50:13
User entered 'No (N)'	(b) (4)	
	Andryelle Toledo (b) (4)	01 Sep 2020 22:17:44
	(b) (4)	

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:22:50**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:25:23

US3892042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:50

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:25:23
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.'	(b) (4) (b) (4), (b) (6)	18 Feb 2021 07:38:03
' (Site from DM).		
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.'	Andryelle Toledo (b) (4)	16 Feb 2021 20:58:35
' answered with 'Yes, subject was assessed for potential Covid-19 infection' (Site from DM).	(b) (4)	
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.'	(b) (4), (b) (6)	15 Feb 2021 12:49:44
' (Site from DM).		
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory tract infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 15:34:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 15:34:17
Data point term sent to Coder	System	25 Nov 2020 15:33:12
User entered 'Upper Respiratory Tract Infection'	Leslie Iverson (b) (4) (b) (4)	25 Nov 2020 15:32:36

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:25:23
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
User entered 'Yes (Y)'	Leslie Iverson (b) (4)	25 Nov 2020 15:32:36

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:25:23
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
User entered 'No (N)'	Leslie Iverson (b) (4)	25 Nov 2020 15:32:36



**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:25:23
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
User entered 'No (N)'	(b) (4) Leslie Iverson (b) (4)	25 Nov 2020 15:32:36

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:25:23
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
User entered '18 Nov 2020'	Leslie Iverson (b) (4)	25 Nov 2020 15:32:36

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:25:23
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
User entered empty.	(b) (4) Leslie Iverson (b) (4)	25 Nov 2020 15:32:36

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:22:50**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:25:23
User entered empty.	System	25 Nov 2020 15:32:36

US3892042

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:22:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:25:23
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
User entered 'No (N)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	25 Jan 2021 15:46:29
User closed query 'Per MM: please provide the end date.' (Site from DM).	(b) (4)	31 Dec 2020 07:38:30
Query 'Per MM: please provide the end date.' answered with 'Subject contacted on 28 Dec. 2020 (Safety Call) and still complains of Mild Cough.' (Site from DM).	Andryelle Toledo (b) (4)	31 Dec 2020 01:21:23
User opened query 'Per MM: please provide the end date.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 18:49:05
User entered 'Yes (Y)'	Leslie Iverson (b) (4)	25 Nov 2020 15:32:36

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:22:50**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:25:23
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
User entered '11 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Andryelle Toledo (b) (4)	25 Jan 2021 15:46:29
User entered empty.	(b) (4)	
	Leslie Iverson (b) (4)	25 Nov 2020 15:32:36
	(b) (4)	

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:22:50**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:25:23
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
User entered empty.	(b) (4) Leslie Iverson (b) (4)	25 Nov 2020 15:32:36

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:22:50**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:25:23
User entered empty.	System	25 Nov 2020 15:32:36



**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:25:23
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
User entered 'Grade 1/Mild (Grade 1/Mild)'	Leslie Iverson (b) (4)	25 Nov 2020 15:32:36

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:25:23
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
User entered 'No (N)'	Leslie Iverson (b) (4)	25 Nov 2020 15:32:36

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:25:23
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
User entered '0'	Leslie Iverson (b) (4)	25 Nov 2020 15:32:36

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:25:23
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
User entered '0'	Leslie Iverson (b) (4)	25 Nov 2020 15:32:36

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:25:23
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
User entered '0'	Leslie Iverson (b) (4)	25 Nov 2020 15:32:36

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:22:50**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:25:23
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
User entered empty.	Leslie Iverson (b) (4)	25 Nov 2020 15:32:36

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:22:50**

**Hospital Discharge Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:25:23
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
User entered empty.	Leslie Iverson (b) (4)	25 Nov 2020 15:32:36

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:25:23
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
User entered empty.	Leslie Iverson (b) (4)	25 Nov 2020 15:32:36



**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:25:23
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
User entered empty.	(b) (4) Leslie Iverson (b) (4)	25 Nov 2020 15:32:36

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:25:23
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
User entered '0'	Leslie Iverson (b) (4)	25 Nov 2020 15:32:36

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:25:23
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
User entered '0'	Leslie Iverson (b) (4)	25 Nov 2020 15:32:36

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:25:23
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
User entered '0'	Leslie Iverson (b) (4)	25 Nov 2020 15:32:36

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:25:23
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Nov 2020 15:32:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 15:32:52
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Leslie Iverson (b) (4)	25 Nov 2020 15:32:52
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Nov 2020 15:32:36
User entered empty.	System	25 Nov 2020 15:32:36
	Leslie Iverson (b) (4)	25 Nov 2020 15:32:36
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:25:23
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Nov 2020 15:32:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 15:32:52
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Leslie Iverson (b) (4)	25 Nov 2020 15:32:52
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Nov 2020 15:32:36
User entered empty.	System	25 Nov 2020 15:32:36
	Leslie Iverson (b) (4)	25 Nov 2020 15:32:36
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:25:23
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Nov 2020 15:32:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 15:32:52
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Leslie Iverson (b) (4)	25 Nov 2020 15:32:52
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Nov 2020 15:32:36
User entered empty.	System	25 Nov 2020 15:32:36
	Leslie Iverson (b) (4)	25 Nov 2020 15:32:36
	(b) (4)	

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:22:50**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:25:23
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
User entered 'I'	Leslie Iverson (b) (4)	25 Nov 2020 15:32:36



**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:25:23
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
User entered '0'	Leslie Iverson (b) (4)	25 Nov 2020 15:32:36

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:25:23
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
User entered '0'	Leslie Iverson (b) (4)	25 Nov 2020 15:32:36

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:25:23
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Andryelle Toledo (b) (4)	25 Jan 2021 15:46:29
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4)	
	Leslie Iverson (b) (4)	25 Nov 2020 15:32:36
	(b) (4)	

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:22:50**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:25:23
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
User entered empty.	(b) (4) Leslie Iverson (b) (4)	25 Nov 2020 15:32:36

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:25:23
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
User entered empty.	(b) (4) Leslie Iverson (b) (4)	25 Nov 2020 15:32:36

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:25:23
User entered '0'	System	25 Nov 2020 15:32:36

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:25:23
User entered 'I'	System	25 Nov 2020 15:32:36

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:25:23



**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:22:50**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 12:47:38
Un-reviewed for Safety.	(b) (4), (b) (6)	11 Mar 2021 12:47:34
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:47
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:43:44
User entered	System	23 Feb 2021 15:43:38
'USA-US209-2021-mRNA-1273-P301000003'		
User entered 'New'	(b) (4), (b) (6)	23 Feb 2021 15:43:38

US3892042

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:50

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 22:52:55
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Spinal fractures and dislocations, PT: Thoracic vertebral fracture, LLT: Thoracic vertebral fracture - version MedDRA\23.0.	Coder Import (b) (4)	22 Feb 2021 23:48:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	22 Feb 2021 23:48:48
Data point term sent to Coder	System	22 Feb 2021 20:26:30
User entered 'Spinal fracture on T11 and T12'	Courtney Jensen (b) (4)	22 Feb 2021 20:25:45
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 22:52:57
User entered 'Yes (Y)'	Courtney Jensen (b) (4)	22 Feb 2021 20:25:45
	(b) (4)	

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:51:06
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
User entered 'No (N)'	Courtney Jensen (b) (4)	22 Feb 2021 20:25:45

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 22:53:03
User entered 'No (N)'	Courtney Jensen (b) (4)	22 Feb 2021 20:25:45
	(b) (4)	

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 22:53:05
User entered '20 Feb 2021'	Courtney Jensen (b) (4)	22 Feb 2021 20:25:45
	(b) (4)	

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:53:10
User entered empty.	Courtney Jensen (b) (4)	22 Feb 2021 20:25:45
	(b) (4)	

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:22:50**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 20:25:45



**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:53:13
User entered 'No (N)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	02 Mar 2021 00:09:40
	(b) (4)	
User entered 'Yes (Y)'	Courtney Jensen (b) (4)	22 Feb 2021 20:25:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:50

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 22:53:39
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	02 Mar 2021 00:09:58
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	02 Mar 2021 00:09:58
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	02 Mar 2021 00:09:40
User entered '23 Feb 2021' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	02 Mar 2021 00:09:40
User entered empty.	(b) (4)	
	Courtney Jensen (b) (4)	22 Feb 2021 20:25:45
	(b) (4)	

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:22:50**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:53:53
User entered empty.	Courtney Jensen (b) (4)	22 Feb 2021 20:25:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:50

[AE End Date and Time \(derived\)](#)

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.' canceled (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 18:20:03
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)	02 Mar 2021 13:50:08
User entered empty.	System	22 Feb 2021 20:25:45

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 22:53:55
User entered 'Grade 3/Severe (Grade 3/Severe)'	Courtney Jensen (b) (4)	22 Feb 2021 20:25:45
	(b) (4)	

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 22:53:57
User entered 'Yes (Y)'	Courtney Jensen (b) (4)	22 Feb 2021 20:25:45
	(b) (4)	

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 22:53:59
User entered '0'	Courtney Jensen (b) (4)	22 Feb 2021 20:25:45
	(b) (4)	

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 22:54:01
User entered '0'	Courtney Jensen (b) (4)	22 Feb 2021 20:25:45
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:50

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 22:54:04
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	26 Feb 2021 12:53:57
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Subject's still in the hospital, because of that discharge date is not completed.' (Site from System).	Andryelle Toledo (b) (4)	23 Feb 2021 16:12:33
	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	22 Feb 2021 20:25:45
User entered 'I'	Courtney Jensen (b) (4)	22 Feb 2021 20:25:45
	(b) (4)	

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:22:50**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 22:54:13
User entered '20 Feb 2021'	Courtney Jensen (b) (4)	22 Feb 2021 20:25:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:50

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 22:54:25
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 17:01:54
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'Update. The discharge date is 23 Feb. 2021' (Site from Safety).	Andryelle Toledo (b) (4)	02 Mar 2021 14:25:50
	(b) (4)	
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 13:49:31
User entered '23 Feb 2021' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	02 Mar 2021 00:09:40
	(b) (4)	
User entered empty.	Courtney Jensen (b) (4)	22 Feb 2021 20:25:45
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:54:38
User entered 'No (N)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	23 Feb 2021 16:11:24
	(b) (4)	
User entered empty.	Courtney Jensen (b) (4)	22 Feb 2021 20:25:45
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 22:54:41
User entered empty.	Courtney Jensen (b) (4)	22 Feb 2021 20:25:45
	(b) (4)	

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 22:54:43
User entered '0'	Courtney Jensen (b) (4)	22 Feb 2021 20:25:45
	(b) (4)	

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:54:45
User entered '0'	Courtney Jensen (b) (4)	22 Feb 2021 20:25:45
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:54:47
User entered '0'	Courtney Jensen (b) (4)	22 Feb 2021 20:25:45
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 22:54:49
User entered 'Not Related (NOT RELATED)'	Courtney Jensen (b) (4)	22 Feb 2021 20:25:45
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 22:54:52
User entered 'Not Related (NOT RELATED)'	Courtney Jensen (b) (4)	22 Feb 2021 20:25:45
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 22:55:08
User entered 'Not Applicable (NOT APPLICABLE)'	Courtney Jensen (b) (4)	22 Feb 2021 20:25:45
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:22:50**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 22:55:10
User entered '0'	Courtney Jensen (b) (4)	22 Feb 2021 20:25:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Mar 2021 14:31:20
	(b) (4)	
DataPoint Un-verified.	Andryelle Toledo (b) (4)	18 Mar 2021 17:43:58
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	18 Mar 2021 17:43:58
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	18 Mar 2021 17:43:58
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:55:12
User entered '0'	Courtney Jensen (b) (4)	22 Feb 2021 20:25:45
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:55:20
User entered 'I'	Courtney Jensen (b) (4)	22 Feb 2021 20:25:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:50

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
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) (4), (b) (6)	03 Mar 2021 15:27:58
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:55:22
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 'updated' (Site from Safety).	Leslie Iverson (b) (4) (b) (4)	02 Mar 2021 17:22:28
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	02 Mar 2021 16:54:50
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)	02 Mar 2021 13:50:50
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	02 Mar 2021 00:09:58
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Feb 2021 17:27:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Feb 2021 17:27:15
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Andryelle Toledo (b) (4) (b) (4)	24 Feb 2021 17:27:15
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Feb 2021 20:25:45
User entered empty.	Courtney Jensen (b) (4) (b) (4)	22 Feb 2021 20:25:45

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 22:55:25
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	02 Mar 2021 17:22:19
User entered 'Pain, physical impairment and surgical changes' reason for change: Data Entry Error	Leslie Iverson (b) (4)	02 Mar 2021 17:22:19
	(b) (4)	
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	02 Mar 2021 16:54:50
User entered empty.	Courtney Jensen (b) (4)	22 Feb 2021 20:25:45
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:50

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:51:14
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
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) (4), (b) (6)	11 Mar 2021 12:47:17
User entered 'SUBJECT CONTACTED FOR DAY 179 SAFETY PHONE CALL AND STATED HE IS CURRENTLY HOSPITALIZED. SUBJECT WENT SLEDDING ON 20FEB2021 AND CRASHED, RESULTING IN FRACTURING HIS SPINE AT T11 AND T12. SUBJECT UNDERWENT SURGERY FOR SPINAL FUSION 22FEB2021. POTENTIAL DISCHARGE FOR TOMORROW. WILL CONTACT SUBJECT ON WEDNESDAY TO FOLLOW UP.	Andryelle Toledo (b) (4) (b) (4)	10 Mar 2021 22:16:32
Subject suffered a spinal fracture on 20 Feb. 2021, and had surgery on 22 Feb. 2021. SAE is closed with sequelae of pain, physical impairment and surgical changes as of date of discharge 23 Feb. 2021. Post-surgical pain is opened as separate AE.		
SARS-COV-2 BY PCR: NEGATIVE. COLLECTED ON 20 FEB. 2021 @ 15:14 MST.' reason for change: Data Entry Error		
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 'I sent a fax with medical records today 10 Mar. 2021' (Site from Safety).	Andryelle Toledo (b) (4) (b) (4)	10 Mar 2021 21:31:19

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 14:07:30
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'Updated' (Site from Safety).	Andryelle Toledo (b) (4)	09 Mar 2021 23:10:40
User entered 'SUBJECT CONTACTED FOR DAY 179 SAFETY PHONE CALL AND STATED HE IS CURRENTLY HOSPITALIZED. SUBJECT WENT SLEDDING ON 20FEB2021 AND CRASHED, RESULTING IN FRACTURING HIS SPINE AT T11 AND T12. SUBJECT UNDERWENT SURGERY FOR SPINAL FUSION 21FEB2021. POTENTIAL DISCHARGE FOR TOMORROW. WILL CONTACT SUBJECT ON WEDNESDAY TO FOLLOW UP.	Andryelle Toledo (b) (4)	09 Mar 2021 23:10:33
SUBJECT WAS DISCHARGED ON 23 FEB. 2021, AS EXPECTED, IN GOOD CONDITION. FRACTURE IS CONSIDERED ONGOING BUT NO LONGER AN SAE.		
SARS-COV-2 BY PCR: NEGATIVE. Collected on 20 Feb. 2021 @ 15:14 MST.' reason for change: Data Entry Error		

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CONTACTED FOR DAY 179 SAFETY PHONE CALL AND STATED HE IS CURRENTLY HOSPITALIZED. SUBJECT WENT SLEDDING ON 20FEB2021 AND CRASHED, RESULTING IN FRACTURING HIS SPINE AT T11 AND T12. SUBJECT UNDERWENT SURGERY FOR SPINAL FUSION 21FEB2021. POTENTIAL DISCHARGE FOR TOMORROW. WILL CONTACT SUBJECT ON WEDNESDAY TO FOLLOW UP.  SUBJECT WAS DISCHARGED ON 23 FEB. 2021, AS EXPECTED, IN GOOD CONDITION. FRACTURE IS CONSIDERED ONGOING BUT NO LONGER AN SAE.  SARS-CoV-2 by PCR: Negative'	Andryelle Toledo (b) (4)	09 Mar 2021 23:09:59
reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 19:28:40
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 22:55:33
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 22:55:28
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 17:01:59
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 14:29:18
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'Waiting to medical records. Records requested yesterday 01 Mar. 2021. Update reported per subject, and collected per PI on Safety Call. ' (Site from Safety).	Andryelle Toledo (b) (4)	

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Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:22:50

[Narrative](#)

Audit	User	Time (GMT)
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)	02 Mar 2021 13:50:28
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 13:49:09
User entered 'SUBJECT CONTACTED FOR DAY 179 SAFETY PHONE CALL AND STATED HE IS CURRENTLY HOSPITALIZED. SUBJECT WENT SLEDDING ON 20FEB2021 AND CRASHED, RESULTING IN FRACTURING HIS SPINE AT T11 AND T12. SUBJECT UNDERWENT SURGERY FOR SPINAL FUSION 21FEB2021. POTENTIAL DISCHARGE FOR TOMORROW. WILL CONTACT SUBJECT ON WEDNESDAY TO FOLLOW UP.	Andryelle Toledo (b) (4)	02 Mar 2021 00:12:15
subject was discharged on 23 Feb. 2021, as expected, in good condition. Fracture is considered ongoing but no longer an SAE.' reason for change: Data Entry Error		
User entered 'SUBJECT CONTACTED FOR DAY 179 SAFETY PHONE CALL AND STATED HE IS CURRENTLY HOSPITALIZED. SUBJECT WENT SLEDDING ON 20FEB2021 AND CRASHED, RESULTING IN FRACTURING HIS SPINE AT T11 AND T12. SUBJECT UNDERWENT SURGERY FOR SPINAL FUSION 21FEB2021. POTENTIAL DISCHARGE FOR TOMORROW. WILL CONTACT SUBJECT ON WEDNESDAY TO FOLLOW UP.' reason for change: Data Entry Error	Courtney Jensen (b) (4)	22 Feb 2021 20:26:34

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject contacted for day 179 safety phone call and stated he is currently hospitalized. Subject went sledding on 02FEB2021 and crashed, resulting in fracturing his spine at T11 and T12. Subject underwent surgery for spinal fusion 21FEB2021. Potential discharge for tomorrow. Will contact subject on Wednesday to follow up.'	Courtney Jensen (b) (4)	22 Feb 2021 20:25:45

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Feb 2021 20:25:45

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Feb 2021 20:25:45

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Feb 2021 16:11:24



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:50

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
	(b) (4)	
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural pain, LLT: Postoperative pain - version MedDRA\23.0.	Coder Import (b) (4)	02 Mar 2021 22:24:58
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Mar 2021 22:24:58
	(b) (4)	
Data point term sent to Coder	System	02 Mar 2021 22:23:20
Coding entries removed.	Andryelle Toledo (b) (4)	02 Mar 2021 22:22:46
	(b) (4)	
User entered 'Post-surgical Pain' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	02 Mar 2021 22:22:46
	(b) (4)	
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Spinal fractures and dislocations, PT: Thoracic vertebral fracture, LLT: Thoracic vertebral fracture - version MedDRA\23.0.	Coder Import (b) (4)	02 Mar 2021 00:30:03
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Mar 2021 00:30:03
	(b) (4)	
Data point term sent to Coder	System	02 Mar 2021 00:28:58
User entered 'SPINAL FRACTURE ON T11 AND T12'	Andryelle Toledo (b) (4)	02 Mar 2021 00:28:43
	(b) (4)	

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:28:43
	(b) (4)	

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:28:43
	(b) (4)	

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:28:43
	(b) (4)	

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
	(b) (4)	
User entered '22 Feb 2021' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	10 Mar 2021 22:09:58
	(b) (4)	
User entered '21 Feb 2021' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	02 Mar 2021 22:22:46
	(b) (4)	
User entered '23 Feb 2021'	Andryelle Toledo (b) (4)	02 Mar 2021 00:28:43
	(b) (4)	

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 00:28:43
	(b) (4)	

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:22:50**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 00:28:43

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:28:43
	(b) (4)	



**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:22:50**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 00:28:43
	(b) (4)	

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:22:50**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 00:28:43
	(b) (4)	

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:22:50**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 00:28:43

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:28:43
	(b) (4)	

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:28:43
	(b) (4)	

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	02 Mar 2021 00:28:43
	(b) (4)	

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	02 Mar 2021 00:28:43
	(b) (4)	

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	02 Mar 2021 00:28:43
	(b) (4)	



**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:22:50**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 00:28:43
	(b) (4)	

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:22:50**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 00:28:43
	(b) (4)	

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 00:28:43
	(b) (4)	

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 00:28:43
	(b) (4)	

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	02 Mar 2021 00:28:43
	(b) (4)	

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	02 Mar 2021 00:28:43
	(b) (4)	

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4) (b) (4)	15 Mar 2021 16:21:45
User entered '0'	Andryelle Toledo (b) (4) (b) (4)	02 Mar 2021 00:28:43

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:50

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Mar 2021 00:28:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Mar 2021 00:28:59
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	02 Mar 2021 00:28:59
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Mar 2021 00:28:43
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 00:28:43
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:50

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Mar 2021 00:28:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Mar 2021 00:28:59
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	02 Mar 2021 00:28:59
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Mar 2021 00:28:43
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 00:28:43
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:50

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Mar 2021 00:28:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Mar 2021 00:28:59
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	02 Mar 2021 00:28:59
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Mar 2021 00:28:43
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 00:28:43
	(b) (4)	

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:22:50**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	02 Mar 2021 00:28:43
	(b) (4)	

US3892042

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:22:50

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed #15 and 16 recorded were given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 13:32:27
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed #15 and 16 recorded were given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify. ' answered with 'Confirm medication for this Event, medication started during hospitalization and extended after discharging. ' (Site from DM).	Andryelle Toledo (b) (4)	29 Mar 2021 19:55:57
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed #15 and 16 recorded were given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	28 Mar 2021 22:11:32
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
User entered 'I'	Andryelle Toledo (b) (4)	02 Mar 2021 00:28:43

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	02 Mar 2021 00:28:43
	(b) (4)	

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:28:43
	(b) (4)	

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:22:50**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 00:28:43
	(b) (4)	

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	15 Mar 2021 16:21:45
	(b) (4)	
User entered 'Pain follow surgery did not prolong hospitalization and it is not an SAE. Surgery date collected based on Medical Records.' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	10 Mar 2021 22:11:22
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 00:28:43
	(b) (4)	



**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Mar 2021 00:28:43

**US3892042**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Mar 2021 00:28:43

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:22:50

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:54:31
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = 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 2, Pain at Injection Site = 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 'Tylenol is the medication associated with this Solicited AE' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 09:36:30
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = 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).	Andryelle Toledo (b) (4) (b) (4)	11 Feb 2021 21:12:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Feb 2021 10:45:06
	Andryelle Toledo (b) (4) (b) (4)	01 Sep 2020 22:17:57

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Sep 2020 22:19:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 22:19:34
Data point term sent to Coder User entered 'IBUPROFEN'	System Andryelle Toledo (b) (4) (b) (4)	01 Sep 2020 22:19:15 01 Sep 2020 22:18:38

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	01 Sep 2020 22:18:38
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'HEADACHES'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	01 Sep 2020 22:18:38

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:50

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:40:20
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 18:37:59
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered '800'	Andryelle Toledo (b) (4)	01 Sep 2020 22:18:38
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'mg (mg)'	Andryelle Toledo (b) (4)	01 Sep 2020 22:18:38
	(b) (4)	



**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:22:50**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	01 Sep 2020 22:18:38
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'as needed (PRN)'	Andryelle Toledo (b) (4)	01 Sep 2020 22:18:38
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:22:50

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	01 Sep 2020 22:18:38
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'Oral (ORAL)'	Andryelle Toledo (b) (4)	01 Sep 2020 22:18:38
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:22:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	01 Sep 2020 22:18:38
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'UN UNK 2000'	Andryelle Toledo (b) (4)	01 Sep 2020 22:18:38
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	01 Sep 2020 22:18:38
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	01 Sep 2020 22:18:38
	(b) (4)	



**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:22:50**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	01 Sep 2020 22:18:38
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	01 Sep 2020 22:18:38
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 22:18:38

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 22:18:38

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 22:18:38

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Oct 2020 14:37:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 14:37:38
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYTREC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 22:21:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 22:21:36
Data point term sent to Coder	System	01 Sep 2020 22:20:16
User entered 'ZYTREC'	Andryelle Toledo (b) (4) (b) (4)	01 Sep 2020 22:19:25

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	01 Sep 2020 22:19:25
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'SEASONAL ALLERGIES'	(b) (4) Andryelle Toledo (b) (4) (b) (4)	01 Sep 2020 22:19:25



**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered '10'	Andryelle Toledo (b) (4)	01 Sep 2020 22:19:25
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'mg (mg)'	Andryelle Toledo (b) (4)	01 Sep 2020 22:19:25
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:50

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	01 Sep 2020 22:19:25
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'as needed (PRN)'	Andryelle Toledo (b) (4)	01 Sep 2020 22:19:25
	(b) (4)	

US3892042

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:22:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	01 Sep 2020 22:19:25
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'Oral (ORAL)'	Andryelle Toledo (b) (4)	01 Sep 2020 22:19:25
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:22:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	01 Sep 2020 22:19:25
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'UN UNK 2012'	Andryelle Toledo (b) (4)	01 Sep 2020 22:19:25
	(b) (4)	



**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	01 Sep 2020 22:19:25
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	01 Sep 2020 22:19:25
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:22:50**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	01 Sep 2020 22:19:25
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:22:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	01 Sep 2020 22:19:25
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 22:19:25

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 22:19:25

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 22:19:25

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:22:50

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:27:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Feb 2021 23:35:10
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Feb 2021 23:35:10
	(b) (4)	
Data point term sent to Coder	System	18 Feb 2021 23:33:48
Coding entries removed.	Andryelle Toledo (b) (4)	18 Feb 2021 23:33:42
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Oct 2020 14:53:42
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	27 Oct 2020 14:53:42
	(b) (4)	
Data point term sent to Coder	System	27 Oct 2020 14:52:14
User entered 'Influenza Vaccine'	Andryelle Toledo (b) (4)	27 Oct 2020 14:51:34
	(b) (4)	



**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:27:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	27 Oct 2020 14:51:34
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:22:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:27:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'prophylaxis for influenza' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	18 Feb 2021 23:33:42
	(b) (4)	
User entered 'influenza'	Andryelle Toledo (b) (4)	27 Oct 2020 14:51:34
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:27:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered '0.5'	Andryelle Toledo (b) (4)	27 Oct 2020 14:51:34
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:27:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'mL (mL)'	Andryelle Toledo (b) (4)	27 Oct 2020 14:51:34
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:22:50**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:27:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	27 Oct 2020 14:51:34
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:27:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'once (ONCE)'	Andryelle Toledo (b) (4)	27 Oct 2020 14:51:34
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:22:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:27:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	27 Oct 2020 14:51:34
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:27:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'Intramuscular (INTRAMUSCULAR)'	Andryelle Toledo (b) (4)	27 Oct 2020 14:51:34
	(b) (4)	



**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:22:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:27:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	27 Oct 2020 14:51:34
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:27:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered '23 Oct 2020'	Andryelle Toledo (b) (4)	27 Oct 2020 14:51:34
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:27:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	27 Oct 2020 14:51:34
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:27:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	27 Oct 2020 14:51:34
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:22:50**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:27:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered '23 Oct 2020'	Andryelle Toledo (b) (4)	27 Oct 2020 14:51:34
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:27:55
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	27 Oct 2020 14:51:34
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:27:55
User entered empty.	System	27 Oct 2020 14:51:34

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:27:55
User entered empty.	System	27 Oct 2020 14:51:34



**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:27:55
User entered empty.	System	27 Oct 2020 14:51:34

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:50

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, PRODUCT: STEROIDS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Nov 2020 06:15:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 06:15:14
Data point term sent to Coder	System	27 Oct 2020 14:59:31
User entered 'Nasal Steroid'	Andryelle Toledo (b) (4) (b) (4)	27 Oct 2020 14:58:40

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:22:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	27 Oct 2020 14:58:40
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:22:50**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'Seasonal Allergies'	Andryelle Toledo (b) (4)	27 Oct 2020 14:58:40
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:22:50**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered '2'	Andryelle Toledo (b) (4)	27 Oct 2020 14:58:40
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:22:50**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'puff (PUFF)'	Andryelle Toledo (b) (4)	27 Oct 2020 14:58:40
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:22:50**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	27 Oct 2020 14:58:40
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:22:50**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'once daily (QD)'	Andryelle Toledo (b) (4)	27 Oct 2020 14:58:40
	(b) (4)	



**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:22:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	27 Oct 2020 14:58:40
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:22:50**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'Nasal (NASAL)'	Andryelle Toledo (b) (4)	27 Oct 2020 14:58:40
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:22:50**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	27 Oct 2020 14:58:40
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:22:50**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered '15 Oct 2020'	Andryelle Toledo (b) (4)	27 Oct 2020 14:58:40
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	27 Oct 2020 14:58:40
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:22:50**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	27 Oct 2020 14:58:40
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:22:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	27 Oct 2020 14:58:40
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:22:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	27 Oct 2020 14:58:40
	(b) (4)	



**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 14:58:40

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 14:58:40

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Oct 2020 14:58:40

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:46
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Mar 2021 19:46:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Mar 2021 19:46:40
	(b) (4)	
Data point term sent to Coder	System	09 Mar 2021 19:45:33
Coding entries removed.	Andryelle Toledo (b) (4)	09 Mar 2021 19:45:23
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 20:26:52
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Dec 2020 20:26:52
	(b) (4)	
Data point term sent to Coder	System	07 Dec 2020 20:26:05
User entered 'Tylenol'	Courtney Jensen (b) (4)	07 Dec 2020 20:25:54
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:22:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:46
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'No (N)'	Courtney Jensen (b) (4)	07 Dec 2020 20:25:54
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:46
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
User closed query 'Per DM CLR: Please note that there is no AE or Dairy event that matches Con med indication of FEVER. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 12:56:38
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 12:56:31
Query 'Per DM CLR: Please note that there is no AE or Dairy event that matches Con med indication of FEVER. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf.' answered with 'Please, see eDiary 2nd dose the first tab, subject reported using medication' (Site from DM).	Andryelle Toledo (b) (4)	09 Mar 2021 22:20:02
Query 'Per DM CLR: Please update the indication to reflect the location and type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'update' (Site from DM).	Andryelle Toledo (b) (4)	09 Mar 2021 19:45:30
Signature has been broken.	Andryelle Toledo (b) (4)	09 Mar 2021 19:45:23
User entered 'PAIN at the injection site AND FEVER' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	09 Mar 2021 19:45:23
User opened query 'Per DM CLR: Please note that there is no AE or Dairy event that matches Con med indication of FEVER. Review if this should be recorded as an Adverse Event (unsolicited). Else, provide clarification if this will not be recorded on AE ecrf.' (Site from DM).	(b) (4), (b) (6)	06 Mar 2021 07:52:30

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:50

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Mar 2021 07:51:50
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 09:36:59
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'Update' (Site from DM).	Andryelle Toledo (b) (4)	09 Feb 2021 17:00:22
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 05:31:21
User entered 'Pain and Fever after injection'	Courtney Jensen (b) (4)	07 Dec 2020 20:25:54

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:22:50**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:46
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered '1000'	Courtney Jensen (b) (4)	07 Dec 2020 20:25:54
	(b) (4)	



US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:46
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'mg (mg)'	Courtney Jensen (b) (4)	07 Dec 2020 20:25:54
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:46
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered empty.	Courtney Jensen (b) (4)	07 Dec 2020 20:25:54
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:22:50**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:46
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'as needed (PRN)'	Courtney Jensen (b) (4)	07 Dec 2020 20:25:54
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:22:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:46
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered empty.	Courtney Jensen (b) (4)	07 Dec 2020 20:25:54
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:22:50**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:46
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'Oral (ORAL)'	Courtney Jensen (b) (4)	07 Dec 2020 20:25:54
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:46
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered empty.	Courtney Jensen (b) (4)	07 Dec 2020 20:25:54
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:46
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered '29 Sep 2020' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	09 Feb 2021 17:00:15
	(b) (4)	
User entered '29 Oct 2020'	Courtney Jensen (b) (4)	07 Dec 2020 20:25:54
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:46
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered '0'	Courtney Jensen (b) (4)	07 Dec 2020 20:25:54
	(b) (4)	



**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:22:50**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:46
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered 'No (N)'	Courtney Jensen (b) (4)	07 Dec 2020 20:25:54
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:46
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered '30 Sep 2020' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	09 Feb 2021 17:00:15
	(b) (4)	
User entered '30 Oct 2020'	Courtney Jensen (b) (4)	07 Dec 2020 20:25:54
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:22:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:46
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of Pain and Fever in eDiary and AE indicates this condition is an Unsolicited event. Review if this should be updated to No.' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 09:37:04
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of Pain and Fever in eDiary and AE indicates this condition is an Unsolicited event. Review if this should be updated to No.' answered with 'Update' (Site from DM).	Andryelle Toledo (b) (4)	09 Feb 2021 17:00:28
	(b) (4)	
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of Pain and Fever in eDiary and AE indicates this condition is an Unsolicited event. Review if this should be updated to No.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 05:31:34
User entered 'Yes (Y)'	Courtney Jensen (b) (4)	07 Dec 2020 20:25:54
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:46
User entered empty.	System	07 Dec 2020 20:25:54

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:46
User entered empty.	System	07 Dec 2020 20:25:54

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:46
User entered empty.	System	07 Dec 2020 20:25:54

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:50

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:33
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE HYDROCHLORIDE, PRODUCTSYNONYM: FLEXERIL [CYCLOBENZAPRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 08:39:56
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 08:39:56
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:56:02
Data point term sent to Coder	System	02 Mar 2021 00:13:41
User entered 'Flexeril'	Andryelle Toledo (b) (4)	02 Mar 2021 00:13:26
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:33
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:56:05
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:13:26
	(b) (4)	



US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:33
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User closed query 'Per DM CLR: Please review AE eCRF's AE #2 SPINAL FRACTURE ON T11 AND T12 (Other Action Taken=Concomitant Procedure); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION/Concomitant Procedure. Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 05:12:02
Query 'Per DM CLR: Please review AE eCRF's AE #2 SPINAL FRACTURE ON T11 AND T12 (Other Action Taken=Concomitant Procedure); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION/Concomitant Procedure. Please update as appropriate.' answered with 'Update' (Site from DM).	Andryelle Toledo (b) (4)	18 Mar 2021 17:46:22
	(b) (4)	
User opened query 'Per DM CLR: Please review AE eCRF's AE #2 SPINAL FRACTURE ON T11 AND T12 (Other Action Taken=Concomitant Procedure); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION/Concomitant Procedure. Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 12:10:05
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:56:25
User entered 'Spinal Fracture'	Andryelle Toledo (b) (4)	02 Mar 2021 00:13:26
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:33
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:56:30
User entered '10'	Andryelle Toledo (b) (4)	02 Mar 2021 00:13:26
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:33
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:56:33
User entered 'mg (mg)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:13:26
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:33
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:56:35
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 00:13:26
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:33
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:56:38
User entered 'as needed (PRN)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:13:26
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:33
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:56:41
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 00:13:26
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:33
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:56:42
User entered 'Oral (ORAL)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:13:26
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:33
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:56:45
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 00:13:26
	(b) (4)	



US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:33
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:56:48
User entered '21 Feb 2021'	Andryelle Toledo (b) (4)	02 Mar 2021 00:13:26
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:33
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:56:52
User entered '0'	Andryelle Toledo (b) (4)	02 Mar 2021 00:13:26
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:33
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:56:55
User entered 'No (N)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	02 Mar 2021 22:24:09
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:13:26
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:33
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User closed query 'Per source note on 01MAR2021, this med is ongoing. kindly confirm which data point is accurate and updated accordingly.' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 15:14:53
Query 'Per source note on 01MAR2021, this med is ongoing. kindly confirm which data point is accurate and updated accordingly.' answered with 'I updated medication. Subject is using Flexeril and Tylenol, however for other indication.' (Site from CRA).	Andryelle Toledo (b) (4)	03 Mar 2021 16:04:45
	(b) (4)	
User opened query 'Per source note on 01MAR2021, this med is ongoing. kindly confirm which data point is accurate and updated accordingly.' (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 23:19:57
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:56:57
User entered '23 Feb 2021' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	02 Mar 2021 22:24:09
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 00:13:26
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:22:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:33
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:57:00
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:13:26
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:33
User entered empty.	System	02 Mar 2021 00:13:26

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:33
User entered empty.	System	02 Mar 2021 00:13:26

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:33
User entered empty.	System	02 Mar 2021 00:13:26



US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:13
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:57:06
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 00:15:01
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 00:15:01
	(b) (4)	
Data point term sent to Coder	System	02 Mar 2021 00:14:42
User entered 'tylenol'	Andryelle Toledo (b) (4)	02 Mar 2021 00:14:28
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:13
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:57:10
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:14:28
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:13
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:57:12
User entered 'Spinal Fracture'	Andryelle Toledo (b) (4)	02 Mar 2021 00:14:28
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:13
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:57:14
User entered '1000'	Andryelle Toledo (b) (4)	02 Mar 2021 00:14:28
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:13
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:57:16
User entered 'mg (mg)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:14:28
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:13
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:57:19
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 00:14:28
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:13
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:57:21
User entered 'three times daily (TID)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:14:28
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:13
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:57:23
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 00:14:28
	(b) (4)	



US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:13
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:05:03
User entered 'Oral (ORAL)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:14:28
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:13
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:05:04
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 00:14:28
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:13
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:10:46
User entered '21 Feb 2021'	Andryelle Toledo (b) (4)	02 Mar 2021 00:14:28
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:13
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:10:48
User entered '0'	Andryelle Toledo (b) (4)	02 Mar 2021 00:14:28
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:13
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:10:50
User entered 'No (N)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	02 Mar 2021 22:24:26
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:14:28
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:13
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User closed query 'Per source note on 01MAR2021, this med is ongoing. kindly confirm which data point is accurate and updated accordingly.' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 15:15:01
Query 'Per source note on 01MAR2021, this med is ongoing. kindly confirm which data point is accurate and updated accordingly.' answered with 'Please see update ' (Site from CRA).	Andryelle Toledo (b) (4)	03 Mar 2021 16:29:47
	(b) (4)	
User opened query 'Per source note on 01MAR2021, this med is ongoing. kindly confirm which data point is accurate and updated accordingly.' (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 23:20:08
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:10:52
User entered '23 Feb 2021' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	02 Mar 2021 22:24:26
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 00:14:28
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:22:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:13
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:10:54
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:14:28
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:13
User entered '3'	System	02 Mar 2021 00:14:28



**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:13
User entered '1'	System	02 Mar 2021 00:14:28

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:13
User entered '804 (804)'	System	02 Mar 2021 00:14:28

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:50

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:36
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Mar 2021 12:06:40
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Mar 2021 12:06:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:11:00
Data point term sent to Coder	System	02 Mar 2021 00:15:43
User entered 'Oxycodone'	Andryelle Toledo (b) (4)	02 Mar 2021 00:15:12
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:36
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:11:03
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:15:12
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:36
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:11:07
User entered 'Spinal Fracture'	Andryelle Toledo (b) (4)	02 Mar 2021 00:15:12
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:36
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:11:09
User entered '5'	Andryelle Toledo (b) (4)	02 Mar 2021 00:15:12
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:36
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:11:13
User entered 'mg (mg)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:15:12
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:36
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:11:15
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 00:15:12
	(b) (4)	



US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:36
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:11:18
User entered 'as needed (PRN)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:15:12
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:36
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:11:20
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 00:15:12
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:36
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:11:22
User entered 'Oral (ORAL)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:15:12
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:36
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:11:24
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 00:15:12
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:36
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:11:26
User entered '21 Feb 2021'	Andryelle Toledo (b) (4)	02 Mar 2021 00:15:12
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:36
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:11:28
User entered '0'	Andryelle Toledo (b) (4)	02 Mar 2021 00:15:12
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:36
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:11:31
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:15:12
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:36
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:11:33
User entered '25 Feb 2021'	Andryelle Toledo (b) (4)	02 Mar 2021 00:15:12
	(b) (4)	



US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:22:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:36
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:11:34
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:15:12
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:36
User entered empty.	System	02 Mar 2021 00:15:12

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:36
User entered empty.	System	02 Mar 2021 00:15:12

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:36
User entered empty.	System	02 Mar 2021 00:15:12

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:50

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:08
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC TROMETHAMINE, PRODUCTSYNONYM: TORADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Mar 2021 14:26:03
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Mar 2021 14:26:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:11:40
Data point term sent to Coder User entered 'Toradol'	System	02 Mar 2021 00:16:44
	Andryelle Toledo (b) (4)	02 Mar 2021 00:15:55
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:08
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:11:44
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:15:55
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:08
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:11:46
User entered 'Spinal Fracture'	Andryelle Toledo (b) (4)	02 Mar 2021 00:15:55
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:08
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:11:50
User entered '15'	Andryelle Toledo (b) (4)	02 Mar 2021 00:15:55
	(b) (4)	



US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:08
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:11:54
User entered 'mg (mg)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:15:55
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:08
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:11:57
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 00:15:55
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:08
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:12:01
User entered 'once daily (QD)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:15:55
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:08
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:12:03
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 00:15:55
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:08
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:12:05
User entered 'Intravenous (INTRAVENOUS)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:15:55
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:08
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:12:07
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 00:15:55
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:08
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:12:10
User entered '21 Feb 2021'	Andryelle Toledo (b) (4)	02 Mar 2021 00:15:55
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:08
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:12:12
User entered '0'	Andryelle Toledo (b) (4)	02 Mar 2021 00:15:55
	(b) (4)	



**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:22:50**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:08
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:12:14
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:15:55
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:08
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:12:16
User entered '22 Feb 2021'	Andryelle Toledo (b) (4)	02 Mar 2021 00:15:55
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:22:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:08
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:12:18
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:15:55
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:08
User entered '1'	System	02 Mar 2021 00:15:55

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:08
User entered '1'	System	02 Mar 2021 00:15:55

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:08
User entered '804 (804)'	System	02 Mar 2021 00:15:55

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:50

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Mar 2021 12:32:51
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Mar 2021 12:32:51
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:12:22
Data point term sent to Coder	System	02 Mar 2021 00:16:46
User entered 'Morphine'	Andryelle Toledo (b) (4)	02 Mar 2021 00:16:37
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:12:26
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:16:37
	(b) (4)	



US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:12:28
User entered 'Spinal Fracture'	Andryelle Toledo (b) (4)	02 Mar 2021 00:16:37
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:12:30
User entered '8'	Andryelle Toledo (b) (4)	02 Mar 2021 00:16:37
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:12:33
User entered 'mg (mg)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:16:37
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:12:35
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 00:16:37
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:12:40
User entered 'once (ONCE)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:16:37
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:12:44
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 00:16:37
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:12:46
User entered 'Intravenous (INTRAVENOUS)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:16:37
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:12:50
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 00:16:37
	(b) (4)	



US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:12:52
User entered '20 Feb 2021'	Andryelle Toledo (b) (4)	02 Mar 2021 00:16:37
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:12:54
User entered '0'	Andryelle Toledo (b) (4)	02 Mar 2021 00:16:37
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:12:59
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:16:37
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:13:01
User entered '20 Feb 2021'	Andryelle Toledo (b) (4)	02 Mar 2021 00:16:37
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:22:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:02
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:13:03
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:16:37
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:02
User entered empty.	System	02 Mar 2021 00:16:37

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:02
User entered empty.	System	02 Mar 2021 00:16:37

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:02
User entered empty.	System	02 Mar 2021 00:16:37



US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:22
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: DIAZEPAM, PRODUCTSYNONYM: VALIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Mar 2021 13:29:57
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Mar 2021 13:29:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:13:07
Data point term sent to Coder User entered 'Valium'	System	02 Mar 2021 00:17:47
	Andryelle Toledo (b) (4)	02 Mar 2021 00:17:18
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:22
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:13:36
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:17:18
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:22
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:13:39
User entered 'Spinal Fracture'	Andryelle Toledo (b) (4)	02 Mar 2021 00:17:18
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:22
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:13:41
User entered '5'	Andryelle Toledo (b) (4)	02 Mar 2021 00:17:18
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:22
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:13:44
User entered 'mg (mg)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:17:18
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:22
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:13:46
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 00:17:18
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:22
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:13:49
User entered 'once (ONCE)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:17:18
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:22
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:13:51
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 00:17:18
	(b) (4)	



US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:22
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:13:53
User entered 'Intravenous (INTRAVENOUS)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:17:18
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:22
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:13:55
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 00:17:18
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:22
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:13:57
User entered '20 Feb 2021'	Andryelle Toledo (b) (4)	02 Mar 2021 00:17:18
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:22
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:13:59
User entered '0'	Andryelle Toledo (b) (4)	02 Mar 2021 00:17:18
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:22
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:14:01
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:17:18
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:22
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:14:04
User entered '20 Feb 2021'	Andryelle Toledo (b) (4)	02 Mar 2021 00:17:18
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:22:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:22
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:14:06
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:17:18
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 10:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:22
User entered empty.	System	02 Mar 2021 00:17:18



**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:22
User entered empty.	System	02 Mar 2021 00:17:18

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:22
User entered empty.	System	02 Mar 2021 00:17:18

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:24
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:14:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 00:20:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 00:20:01
Data point term sent to Coder	System	02 Mar 2021 00:18:49
User entered 'Dilaudid'	Andryelle Toledo (b) (4) (b) (4)	02 Mar 2021 00:18:05

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:24
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:14:15
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:18:05
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:24
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:14:18
User entered 'Spinal Fracture'	Andryelle Toledo (b) (4)	02 Mar 2021 00:18:05
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:24
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:14:19
User entered '1'	Andryelle Toledo (b) (4)	02 Mar 2021 00:18:05
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:24
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:14:22
User entered 'mg (mg)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:18:05
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:24
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:14:24
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 00:18:05
	(b) (4)	



US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:24
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:14:26
User entered 'once (ONCE)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:18:05
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:24
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:14:28
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 00:18:05
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:24
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:14:30
User entered 'Intravenous (INTRAVENOUS)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:18:05
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:24
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:14:32
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 00:18:05
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:24
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:14:34
User entered '20 Feb 2021'	Andryelle Toledo (b) (4)	02 Mar 2021 00:18:05
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:24
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:14:36
User entered '0'	Andryelle Toledo (b) (4)	02 Mar 2021 00:18:05
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 10:22:50**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:24
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:14:38
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:18:05
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:24
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:14:40
User entered '20 Feb 2021'	Andryelle Toledo (b) (4)	02 Mar 2021 00:18:05
	(b) (4)	



US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:22:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:24
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:14:43
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:18:05
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 10:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:24
User entered empty.	System	02 Mar 2021 00:18:05

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:24
User entered empty.	System	02 Mar 2021 00:18:05

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:24
User entered empty.	System	02 Mar 2021 00:18:05

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:22:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:58:57
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Mar 2021 12:05:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Mar 2021 12:05:55
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, ATC: OTHER MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 10:06:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 10:06:13
Data point term sent to Coder User entered 'Botox'	System Andryelle Toledo (b) (4)	02 Mar 2021 00:19:50 02 Mar 2021 00:18:52

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:22:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:58:57
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	02 Mar 2021 00:18:52

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:22:50**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:58:57
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
User entered 'Elective Cosmetic Procedure'	Andryelle Toledo (b) (4)	02 Mar 2021 00:18:52

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:22:50**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:58:57
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
User entered '66'	(b) (4) Andryelle Toledo (b) (4)	02 Mar 2021 00:18:52



**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:22:50**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:58:57
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
User entered 'IU (IU)'	(b) (4) Andryelle Toledo (b) (4)	02 Mar 2021 00:18:52

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:22:50**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:58:57
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Mar 2021 00:18:52

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:22:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:58:57
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
User entered 'once (ONCE)'	(b) (4) Andryelle Toledo (b) (4)	02 Mar 2021 00:18:52

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:22:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:58:57
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Mar 2021 00:18:52

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:22:50**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:58:57
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Andryelle Toledo (b) (4)	02 Mar 2021 00:18:52
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:22:50**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:58:57
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Mar 2021 00:18:52

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:22:50**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:58:57
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
User entered 'un Jan 2021'	(b) (4) Andryelle Toledo (b) (4)	02 Mar 2021 00:18:52

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:58:57
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
User entered '0'	(b) (4) Andryelle Toledo (b) (4)	02 Mar 2021 00:18:52



**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:22:50**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:58:57
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	02 Mar 2021 00:18:52

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:22:50**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:58:57
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
User entered 'un Jan 2021'	(b) (4) Andryelle Toledo (b) (4)	02 Mar 2021 00:18:52

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:22:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:58:57
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	02 Mar 2021 00:18:52

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:58:57
User entered empty.	System	02 Mar 2021 00:18:52

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:58:57
User entered empty.	System	02 Mar 2021 00:18:52

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:58:57
User entered empty.	System	02 Mar 2021 00:18:52

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:59:01
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
User closed query 'Per DM CLR: Please review CM and confirm if this is a duplicate of CM# 13. If yes, please ensure only one entry is recorded. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 05:12:38
Query 'Per DM CLR: Please review CM and confirm if this is a duplicate of CM# 13. If yes, please ensure only one entry is recorded. ' answered with 'These were separate Botox applications--one in January 2020 and the second, during the study, in January 2021.' (Site from DM).	Leslie Iverson (b) (4) (b) (4)	18 Mar 2021 20:57:05
User opened query 'Per DM CLR: Please review CM and confirm if this is a duplicate of CM# 13. If yes, please ensure only one entry is recorded. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 12:10:22
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 12:05:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 12:05:56
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, ATC: OTHER MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 09:50:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 09:50:18
Data point term sent to Coder	System	02 Mar 2021 00:19:52

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:50

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Botox'	Andryelle Toledo (b) (4)	02 Mar 2021 00:19:34
	(b) (4)	



**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 10:22:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:59:01
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
User entered 'No (N)'	(b) (4) Andryelle Toledo (b) (4)	02 Mar 2021 00:19:34

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 10:22:50**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:59:01
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
User entered 'Elective Cosmetic Procedure'	Andryelle Toledo (b) (4)	02 Mar 2021 00:19:34

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 10:22:50**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:59:01
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
User entered '66'	Andryelle Toledo (b) (4)	02 Mar 2021 00:19:34

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 10:22:50**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:59:01
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
User entered 'IU (IU)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:19:34

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 10:22:50**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:59:01
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Mar 2021 00:19:34

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:59:01
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
User entered 'once (ONCE)'	(b) (4) Andryelle Toledo (b) (4)	02 Mar 2021 00:19:34

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:59:01
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Mar 2021 00:19:34

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 10:22:50**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:59:01
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
User entered 'Intramuscular (INTRAMUSCULAR)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:19:34



US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:22:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:59:01
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
User entered empty.	(b) (4) Andryelle Toledo (b) (4)	02 Mar 2021 00:19:34

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 10:22:50**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:59:01
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
User entered 'un Jan 2020'	(b) (4) Andryelle Toledo (b) (4)	02 Mar 2021 00:19:34

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 10:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:59:01
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
User entered '0'	Andryelle Toledo (b) (4)	02 Mar 2021 00:19:34

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 10:22:50**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:59:01
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:19:34

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 10:22:50**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:59:01
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
User entered 'un Jan 2020'	(b) (4) Andryelle Toledo (b) (4)	02 Mar 2021 00:19:34

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 10:22:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:59:01
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Mar 2021 00:19:34

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 10:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:59:01
User entered empty.	System	02 Mar 2021 00:19:34

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:59:01
User entered empty.	System	02 Mar 2021 00:19:34



**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:59:01
User entered empty.	System	02 Mar 2021 00:19:34

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:22:50

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:25
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE HYDROCHLORIDE, PRODUCTSYNONYM: FLEXERIL [CYCLOBENZAPRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 08:39:55
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 08:39:55
	(b) (4)	
Data point term sent to Coder	System	02 Mar 2021 22:26:23
User entered 'Flexeril'	Andryelle Toledo (b) (4)	02 Mar 2021 22:26:09
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 10:22:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:25
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Mar 2021 22:26:09
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:22:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:25
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered 'Post surgical pain'	Andryelle Toledo (b) (4)	02 Mar 2021 22:26:09
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 10:22:50**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:25
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered '10'	Andryelle Toledo (b) (4)	02 Mar 2021 22:26:09
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 10:22:50**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:25
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered 'mg (mg)'	Andryelle Toledo (b) (4)	02 Mar 2021 22:26:09
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:22:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:25
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 22:26:09
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 10:22:50**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:25
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered 'as needed (PRN)'	Andryelle Toledo (b) (4)	02 Mar 2021 22:26:09
	(b) (4)	



US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:22:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:25
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 22:26:09
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 10:22:50**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:25
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered 'Oral (ORAL)'	Andryelle Toledo (b) (4)	02 Mar 2021 22:26:09
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:22:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:25
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 22:26:09
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:22:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:25
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered '21 Feb 2021'	Andryelle Toledo (b) (4)	02 Mar 2021 22:26:09
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 10:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:25
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	02 Mar 2021 22:26:09
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:22:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:25
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	30 Mar 2021 13:44:06
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	02 Mar 2021 22:26:09
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:22:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:25
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered '18 Mar 2021' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	30 Mar 2021 13:44:06
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 22:26:09
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 10:22:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:25
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Mar 2021 22:26:09
	(b) (4)	



**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 10:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:25
User entered empty.	System	02 Mar 2021 22:26:09

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:25
User entered empty.	System	02 Mar 2021 22:26:09

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:25
User entered empty.	System	02 Mar 2021 22:26:09

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:22:50

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:27
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 22:28:47
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Mar 2021 22:28:47
	(b) (4)	
Data point term sent to Coder	System	02 Mar 2021 22:27:25
User entered 'Tylenol'	Andryelle Toledo (b) (4)	02 Mar 2021 22:27:02
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 10:22:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:27
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Mar 2021 22:27:02
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 10:22:50**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:27
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered 'Post surgical pain'	Andryelle Toledo (b) (4)	02 Mar 2021 22:27:02
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:22:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:27
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered '1000'	Andryelle Toledo (b) (4)	02 Mar 2021 22:27:02
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:22:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:27
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered 'mg (mg)'	Andryelle Toledo (b) (4)	02 Mar 2021 22:27:02
	(b) (4)	



US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:22:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:27
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 22:27:02
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 10:22:50**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:27
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered 'as needed (PRN)'	Andryelle Toledo (b) (4)	02 Mar 2021 22:27:02
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:22:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:27
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 22:27:02
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 10:22:50**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:27
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered 'Oral (ORAL)'	Andryelle Toledo (b) (4)	02 Mar 2021 22:27:02
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:22:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:27
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 22:27:02
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:22:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:27
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered '21 Feb 2021'	Andryelle Toledo (b) (4)	02 Mar 2021 22:27:02
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 10:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:27
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	02 Mar 2021 22:27:02
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:22:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:27
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:40:20
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	23 Apr 2021 18:37:01
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 18:37:01
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	02 Mar 2021 22:27:02
	(b) (4)	



US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:22:50

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:27
User signature succeeded.	Michael Adams (b) (4)	26 Apr 2021 22:40:20
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	23 Apr 2021 18:37:01
User entered '18 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 18:37:01
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	02 Mar 2021 22:27:02
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:22:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:27
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	02 Mar 2021 22:27:02
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 10:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:27
User entered empty.	System	02 Mar 2021 22:27:02

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:27
User entered empty.	System	02 Mar 2021 22:27:02

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:27
User entered empty.	System	02 Mar 2021 22:27:02

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:22:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:59
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL, PRODUCTSYNONYM: POLYETHYLENE GLYCOL [MACROGOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 11:48:31
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 11:48:31
	(b) (4)	
Data point term sent to Coder	System	09 Mar 2021 22:59:05
User entered 'Polyethylene Glycol'	Andryelle Toledo (b) (4)	09 Mar 2021 22:58:43
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:22:50**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:59
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered 'Yes (Y)'	Andryelle Toledo (b) (4)	09 Mar 2021 22:58:43
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:22:50

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:59
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
User closed query 'Per DM CLR:Indication= Prophylaxis. Please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis as there is an AE and Con Proc recorded that matches this medication and used within the same timeframe. . Please update as appropriate. Else, clarify.' (Site from DM).	(b) (4)	30 Mar 2021 12:32:20
Query 'Per DM CLR:Indication= Prophylaxis. Please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis as there is an AE and Con Proc recorded that matches this medication and used within the same timeframe. . Please update as appropriate. Else, clarify.' answered with 'Confirm indication' (Site from DM).	Andryelle Toledo (b) (4)	29 Mar 2021 18:53:27
User opened query 'Per DM CLR:Indication= Prophylaxis. Please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis as there is an AE and Con Proc recorded that matches this medication and used within the same timeframe. . Please update as appropriate. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 08:51:00
User entered 'Bowel Prophylaxis'	Andryelle Toledo (b) (4)	09 Mar 2021 22:58:43



**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:22:50**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:59
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered '17'	Andryelle Toledo (b) (4)	09 Mar 2021 22:58:43
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:22:50**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:59
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered 'g (g)'	Andryelle Toledo (b) (4)	09 Mar 2021 22:58:43
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:22:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:59
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	09 Mar 2021 22:58:43
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:22:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:59
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered 'twice daily (BID)'	Andryelle Toledo (b) (4)	09 Mar 2021 22:58:43
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:22:50**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:59
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	09 Mar 2021 22:58:43
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:22:50**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:59
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered 'Oral (ORAL)'	Andryelle Toledo (b) (4)	09 Mar 2021 22:58:43
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:22:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:59
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered empty.	Andryelle Toledo (b) (4)	09 Mar 2021 22:58:43
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:22:50**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:59
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered '20 Feb 2021'	Andryelle Toledo (b) (4)	09 Mar 2021 22:58:43
	(b) (4)	



**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:22:50**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:59
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered '0'	Andryelle Toledo (b) (4)	09 Mar 2021 22:58:43
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:22:50**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:59
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	09 Mar 2021 22:58:43
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:22:50**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:59
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered '23 Feb 2021'	Andryelle Toledo (b) (4)	09 Mar 2021 22:58:43
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:22:50**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:59
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
User entered 'No (N)'	Andryelle Toledo (b) (4)	09 Mar 2021 22:58:43
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:59
User entered '2'	System	09 Mar 2021 22:58:43

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:59
User entered '1'	System	09 Mar 2021 22:58:43

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:59
User entered '804 (804)'	System	09 Mar 2021 22:58:43

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:22:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:52
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:45:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM HYDROCHLORIDE, PRODUCTSYNONYM: VERSED - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 07:06:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 07:06:40
Data point term sent to Coder	System	09 Mar 2021 23:05:09
User entered 'Versed'	Andryelle Toledo (b) (4) (b) (4)	09 Mar 2021 23:05:00



US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:22:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:52
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:45:30
User entered 'No (N)'	Andryelle Toledo (b) (4)	09 Mar 2021 23:05:00
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:22:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:52
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:45:32
User closed query 'Per DM CLR: CM #18,19,20,21; Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 10:41:09
Query 'Per DM CLR: CM #18,19,20,21; Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification. ' answered with 'Medication used during hospitalization - Spinal fracture. The conc. med. is corrected related with AE, and medical records.' (Site from DM).	Andryelle Toledo (b) (4)	29 Mar 2021 19:03:56
User opened query 'Per DM CLR: CM #18,19,20,21; Please review corresponding AE as this does not indicate "Other Action Taken = Concomitant Medication", please review AE entry and tick Concomitant Medication to reflect the CM given. Update as appropriate or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 15:56:21
User entered 'Spinal Fracture'	Andryelle Toledo (b) (4)	09 Mar 2021 23:05:00

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:22:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:52
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:45:33
User entered '5'	Andryelle Toledo (b) (4)	09 Mar 2021 23:05:00
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:22:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:52
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:45:35
User entered 'mg (mg)'	Andryelle Toledo (b) (4)	09 Mar 2021 23:05:00
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:22:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:52
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:45:36
User entered empty.	Andryelle Toledo (b) (4)	09 Mar 2021 23:05:00
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:22:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:52
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:45:37
User entered 'once (ONCE)'	Andryelle Toledo (b) (4)	09 Mar 2021 23:05:00
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:22:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:52
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:45:39
User entered empty.	Andryelle Toledo (b) (4)	09 Mar 2021 23:05:00
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:22:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:52
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:45:40
User entered 'Intramuscular (INTRAMUSCULAR)'	Andryelle Toledo (b) (4)	09 Mar 2021 23:05:00
	(b) (4)	



US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:22:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:52
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:45:42
User entered empty.	Andryelle Toledo (b) (4)	09 Mar 2021 23:05:00
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:22:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:52
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:45:43
User entered '20 Feb 2021'	Andryelle Toledo (b) (4)	09 Mar 2021 23:05:00
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:22:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:52
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:45:45
User entered '0'	Andryelle Toledo (b) (4)	09 Mar 2021 23:05:00
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:22:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:52
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:45:47
User entered 'No (N)'	Andryelle Toledo (b) (4)	09 Mar 2021 23:05:00
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:22:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:52
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:45:49
User entered '20 Feb 2021'	Andryelle Toledo (b) (4)	09 Mar 2021 23:05:00
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:22:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:52
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:45:50
User entered 'No (N)'	Andryelle Toledo (b) (4)	09 Mar 2021 23:05:00
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 10:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:52
User entered empty.	System	09 Mar 2021 23:05:00

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:52
User entered empty.	System	09 Mar 2021 23:05:00



US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:22:50

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:52
User entered empty.	System	09 Mar 2021 23:05:00

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:22:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:53
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:45:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Mar 2021 12:12:00
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Mar 2021 12:12:00
	(b) (4)	
Data point term sent to Coder	System	09 Mar 2021 23:06:09
User entered 'Hydromorphone'	Andryelle Toledo (b) (4)	09 Mar 2021 23:06:01
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:22:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:53
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:45:59
User entered 'No (N)'	Andryelle Toledo (b) (4)	09 Mar 2021 23:06:01
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:22:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:53
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:46:00
User entered 'Spinal Fracture'	Andryelle Toledo (b) (4)	09 Mar 2021 23:06:01
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:22:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:53
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:46:02
User entered '1'	Andryelle Toledo (b) (4)	09 Mar 2021 23:06:01
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:22:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:53
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:46:03
User entered 'mg (mg)'	Andryelle Toledo (b) (4)	09 Mar 2021 23:06:01
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:22:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:53
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:46:05
User entered empty.	Andryelle Toledo (b) (4)	09 Mar 2021 23:06:01
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:22:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:53
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:46:06
User entered 'once (ONCE)'	Andryelle Toledo (b) (4)	09 Mar 2021 23:06:01
	(b) (4)	



US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:22:50

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:53
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:46:08
User entered empty.	Andryelle Toledo (b) (4)	09 Mar 2021 23:06:01
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:22:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:53
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:46:09
User entered 'Intramuscular (INTRAMUSCULAR)'	Andryelle Toledo (b) (4)	09 Mar 2021 23:06:01
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:22:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:53
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:46:11
User entered empty.	Andryelle Toledo (b) (4)	09 Mar 2021 23:06:01
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:22:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:53
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:46:13
User entered '20 Feb 2021'	Andryelle Toledo (b) (4)	09 Mar 2021 23:06:01
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:22:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:53
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:46:15
User entered '0'	Andryelle Toledo (b) (4)	09 Mar 2021 23:06:01
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:22:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:53
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:46:17
User entered 'No (N)'	Andryelle Toledo (b) (4)	09 Mar 2021 23:06:01
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:22:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:53
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:46:19
User entered '20 Feb 2021'	Andryelle Toledo (b) (4)	09 Mar 2021 23:06:01
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:22:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:53
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:46:21
User entered 'No (N)'	Andryelle Toledo (b) (4)	09 Mar 2021 23:06:01
	(b) (4)	



**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 10:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:53
User entered empty.	System	09 Mar 2021 23:06:01

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:53
User entered empty.	System	09 Mar 2021 23:06:01

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:28:53
User entered empty.	System	09 Mar 2021 23:06:01

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:22:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:12
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:46:28
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: ANESTHETICS, GENERAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 07:30:53
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 07:30:53
	(b) (4)	
Data point term sent to Coder	System	09 Mar 2021 23:07:11
User entered 'Endotracheal anesthesia'	Andryelle Toledo (b) (4)	09 Mar 2021 23:07:06
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:22:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:12
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:46:30
User entered 'No (N)'	Andryelle Toledo (b) (4)	09 Mar 2021 23:07:06
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:22:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:12
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:46:32
User entered 'spinal Fracture'	Andryelle Toledo (b) (4)	09 Mar 2021 23:07:06
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:22:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:12
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:46:34
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of dose count if known, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 10:41:25
Query 'Per DM CLR: Please provide the actual dose for this medication instead of dose count if known, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. Else, clarify. ' answered with 'Per PI dose is UNK' (Site from DM).	Andryelle Toledo (b) (4)	29 Mar 2021 19:56:32
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of dose count if known, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 16:10:03
User entered 'I'	Andryelle Toledo (b) (4)	09 Mar 2021 23:07:06

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:22:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:12
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:46:36
User entered 'Other (OTHER)'	Andryelle Toledo (b) (4)	09 Mar 2021 23:07:06
	(b) (4)	



US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:22:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:12
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:46:38
User entered 'dose'	Andryelle Toledo (b) (4)	09 Mar 2021 23:07:06
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:22:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:12
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:46:39
User entered 'once (ONCE)'	Andryelle Toledo (b) (4)	09 Mar 2021 23:07:06
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:22:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:12
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:46:41
User entered empty.	Andryelle Toledo (b) (4)	09 Mar 2021 23:07:06
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:22:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:12
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:46:43
User entered 'Intravenous (INTRAVENOUS)'	Andryelle Toledo (b) (4)	09 Mar 2021 23:07:06
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:22:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:12
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:46:45
User entered empty.	Andryelle Toledo (b) (4)	09 Mar 2021 23:07:06
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:22:50

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:12
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:46:46
User entered '22 Feb 2021'	Andryelle Toledo (b) (4)	09 Mar 2021 23:07:06
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:22:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:12
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:46:48
User entered '0'	Andryelle Toledo (b) (4)	09 Mar 2021 23:07:06
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:22:50

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:12
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:46:50
User entered 'No (N)'	Andryelle Toledo (b) (4)	09 Mar 2021 23:07:06
	(b) (4)	



**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 10:22:50**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:12
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:46:52
User entered '22 Feb 2021'	Andryelle Toledo (b) (4)	09 Mar 2021 23:07:06
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:22:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:12
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:46:53
User entered 'No (N)'	Andryelle Toledo (b) (4)	09 Mar 2021 23:07:06
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 10:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:12
User entered empty.	System	09 Mar 2021 23:07:06

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:12
User entered empty.	System	09 Mar 2021 23:07:06

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:12
User entered empty.	System	09 Mar 2021 23:07:06

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:22:50

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:14
	(b) (4)	
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:47:00
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Mar 2021 07:07:46
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Mar 2021 07:07:46
	(b) (4)	
Data point term sent to Coder	System	09 Mar 2021 23:08:12
User entered 'Vancomycin Powder'	Andryelle Toledo (b) (4)	09 Mar 2021 23:08:06
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:22:50

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:14
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:47:02
User entered 'No (N)'	Andryelle Toledo (b) (4)	09 Mar 2021 23:08:06
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:22:50

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:14
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:47:04
User entered 'Spinal Fracture'	Andryelle Toledo (b) (4)	09 Mar 2021 23:08:06
	(b) (4)	



US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:22:50

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:14
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:47:06
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of dose count if known, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 10:41:36
Query 'Per DM CLR: Please provide the actual dose for this medication instead of dose count if known, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. Else, clarify. ' answered with 'Per PI dose is UNK' (Site from DM).	Andryelle Toledo (b) (4)	29 Mar 2021 19:56:50
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of dose count if known, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 16:10:52
User entered 'I'	Andryelle Toledo (b) (4)	09 Mar 2021 23:08:06

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:22:50

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:14
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:47:09
User entered 'Other (OTHER)'	Andryelle Toledo (b) (4)	09 Mar 2021 23:08:06
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:22:50

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:14
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:47:10
User entered 'dose'	Andryelle Toledo (b) (4)	09 Mar 2021 23:08:06
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:22:50

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:14
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:47:12
User entered 'once (ONCE)'	Andryelle Toledo (b) (4)	09 Mar 2021 23:08:06
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:22:50

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:14
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:47:15
User entered empty.	Andryelle Toledo (b) (4)	09 Mar 2021 23:08:06
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:22:50

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:14
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:47:17
User entered 'Other (OTHER)'	Andryelle Toledo (b) (4)	09 Mar 2021 23:08:06
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:22:50

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:14
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:47:19
User entered 'Intra-operative'	Andryelle Toledo (b) (4)	09 Mar 2021 23:08:06
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 10:22:50**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:14
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:47:21
User entered '22 Feb 2021'	Andryelle Toledo (b) (4)	09 Mar 2021 23:08:06
	(b) (4)	



US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:22:50

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:14
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:47:22
User entered '0'	Andryelle Toledo (b) (4)	09 Mar 2021 23:08:06
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 10:22:50**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:14
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:47:24
User entered 'No (N)'	Andryelle Toledo (b) (4)	09 Mar 2021 23:08:06
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:22:50

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:14
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:47:26
User entered '22 Feb 2021'	Andryelle Toledo (b) (4)	09 Mar 2021 23:08:06
	(b) (4)	

US3892042

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:22:50

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:14
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:47:27
User entered 'No (N)'	Andryelle Toledo (b) (4)	09 Mar 2021 23:08:06
	(b) (4)	

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 10:22:50**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:14
User entered empty.	System	09 Mar 2021 23:08:06

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:14
User entered empty.	System	09 Mar 2021 23:08:06

**US3892042**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 10:22:50**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:29:14
User entered empty.	System	09 Mar 2021 23:08:06

**US3892042**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 10 Jun 2021 10:22:50**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:54:31
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:15:07
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	23 Feb 2021 00:05:26
User entered 'No (N)'	Andryelle Toledo (b) (4)	01 Sep 2020 22:19:38
	(b) (4)	



US3892042

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:22:50

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 22:48:05
DataPoint Un-verified.	Andryelle Toledo (b) (4)	10 Mar 2021 22:03:20
	(b) (4)	
Signature has been broken.	Andryelle Toledo (b) (4)	10 Mar 2021 22:03:20
	(b) (4)	
User entered '22 Feb 2021' reason for change: Data Entry Error	Andryelle Toledo (b) (4)	10 Mar 2021 22:03:20
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:15:46
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered '21 Feb 2021'	Andryelle Toledo (b) (4)	23 Feb 2021 00:07:21
	(b) (4)	

**US3892042**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:15:46
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Spinal Fusion'	Andryelle Toledo (b) (4)	23 Feb 2021 00:07:21

**US3892042**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:15:46
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'Adverse Event (AE)'	Andryelle Toledo (b) (4)	23 Feb 2021 00:07:21

**US3892042**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 10:22:50**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 23:15:46
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered empty.	Andryelle Toledo (b) (4)	23 Feb 2021 00:07:21

**US3892042**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 10:22:50**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:29:59
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:48:05
User entered '20 Feb 2021'	Andryelle Toledo (b) (4)	10 Mar 2021 22:04:19

US3892042

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:22:50

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:29:59
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:48:05
User entered 'Cervical, Thoracic, and Lumbar X-Ray'	Andryelle Toledo (b) (4) (b) (4)	10 Mar 2021 22:04:19

**US3892042**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:29:59
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:48:05
User entered 'Diagnostic (DIAGNOSTIC)'	Andryelle Toledo (b) (4) (b) (4)	10 Mar 2021 22:04:19

**US3892042**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 10:22:50**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:29:59
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:48:05
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	10 Mar 2021 22:04:19



**US3892042**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 10:22:50**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:03
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:48:05
User entered '20 Feb 2021'	Andryelle Toledo (b) (4)	10 Mar 2021 22:05:10

**US3892042**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:03
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:48:05
User entered 'Lumbar CT Scan (Without Contrast)'	Andryelle Toledo (b) (4) (b) (4)	10 Mar 2021 22:05:10

**US3892042**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:03
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:48:05
User entered 'Diagnostic (DIAGNOSTIC)'	Andryelle Toledo (b) (4) (b) (4)	10 Mar 2021 22:05:10

**US3892042**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 10:22:50**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:03
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:48:05
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	10 Mar 2021 22:05:10

**US3892042**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 10 Jun 2021 10:22:50**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:08
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 22:48:05
User entered '20 Feb 2021'	Andryelle Toledo (b) (4)	10 Mar 2021 22:05:37
	(b) (4)	

**US3892042**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 10 Jun 2021 10:22:50**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:08
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 22:48:05
User entered 'Chest X-Ray'	Andryelle Toledo (b) (4)	10 Mar 2021 22:05:37
	(b) (4)	

**US3892042**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 10 Jun 2021 10:22:50**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:08
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:48:05
User entered 'Diagnostic (DIAGNOSTIC)'	Andryelle Toledo (b) (4) (b) (4)	10 Mar 2021 22:05:37

**US3892042**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 10 Jun 2021 10:22:50**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:08
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Mar 2021 22:48:05
User entered empty.	Andryelle Toledo (b) (4) (b) (4)	10 Mar 2021 22:05:37



**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'USA-US209-2021-MRNA-1273-P301000003'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Yes (Y)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Yes (Y)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38



**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Michael'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Adams'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered '5251 S Green St'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Murray'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'UT'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered '84123'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 16:34:46
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'US'	(b) (4) System	23 Feb 2021 15:48:58

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Mar 2021 13:51:38
User entered '6'	System	11 Mar 2021 12:48:05
User entered '5'	System	10 Mar 2021 14:08:19
User entered '4'	System	03 Mar 2021 15:32:51
User entered '3'	System	02 Mar 2021 17:02:50
Signature has been broken.	System	25 Feb 2021 16:34:58
User entered '2'	System	25 Feb 2021 16:34:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered '1'	System	23 Feb 2021 15:48:58



**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'USA-US209-2021-MRNA-1273-P301000003'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Yes (Y)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Yes (Y)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38



**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Michael'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Adams'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered '5251 S Green St'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Murray'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'UT'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered '84123'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 16:34:46
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'US'	(b) (4) System	23 Feb 2021 15:48:58

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Mar 2021 13:51:38
User entered '6'	System	11 Mar 2021 12:48:05
User entered '5'	System	10 Mar 2021 14:08:19
User entered '4'	System	03 Mar 2021 15:32:51
User entered '3'	System	02 Mar 2021 17:02:50
Signature has been broken.	System	25 Feb 2021 16:34:58
User entered '2'	System	25 Feb 2021 16:34:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered '1'	System	23 Feb 2021 15:48:58



**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 10:22:50**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered '23/Feb/2021 15:48'	(b) (4) System	23 Feb 2021 15:48:58

US3892042

Folder: SAE USA-US209-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:22:50

**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)	02 Mar 2021 22:52:10
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 16:34:46
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'I'	(b) (4), (b) (6)	23 Feb 2021 15:48:58

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'USA-US209-2021-MRNA-1273-P301000003'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Yes (Y)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Yes (Y)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38



**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Michael'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Adams'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered '5251 S Green St'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Murray'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'UT'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered '84123'	System	23 Feb 2021 15:43:38



**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 16:34:46
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'US'	(b) (4) System	23 Feb 2021 15:48:58

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Mar 2021 13:51:38
User entered '6'	System	11 Mar 2021 12:48:05
User entered '5'	System	10 Mar 2021 14:08:19
User entered '4'	System	03 Mar 2021 15:32:51
User entered '3'	System	02 Mar 2021 17:02:50
Signature has been broken.	System	25 Feb 2021 16:34:58
User entered '2'	System	25 Feb 2021 16:34:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered '1'	System	23 Feb 2021 15:48:58

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 10:22:50**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User entered '25/Feb/2021 11:34'	System	25 Feb 2021 16:34:58

US3892042

Folder: SAE USA-US209-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:22:50

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 17:02:35
User entered 'I'	(b) (4), (b) (6)	25 Feb 2021 16:34:58

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'USA-US209-2021-MRNA-1273-P301000003'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Yes (Y)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38



**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Yes (Y)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Michael'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Adams'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered '5251 S Green St'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Murray'	System	23 Feb 2021 15:43:38



**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'UT'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered '84123'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 16:34:46
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'US'	(b) (4) System	23 Feb 2021 15:48:58

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Mar 2021 13:51:38
User entered '6'	System	11 Mar 2021 12:48:05
User entered '5'	System	10 Mar 2021 14:08:19
User entered '4'	System	03 Mar 2021 15:32:51
User entered '3'	System	02 Mar 2021 17:02:50
Signature has been broken.	System	25 Feb 2021 16:34:58
User entered '2'	System	25 Feb 2021 16:34:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered '1'	System	23 Feb 2021 15:48:58

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 10:22:50**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User entered '02/Mar/2021 11:02'	System	02 Mar 2021 17:02:50

US3892042

Folder: SAE USA-US209-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:22:50

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	03 Mar 2021 15:32:40
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User entered 'I'	(b) (4), (b) (6)	02 Mar 2021 17:02:50

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'USA-US209-2021-MRNA-1273-P301000003'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Yes (Y)'	System	23 Feb 2021 15:43:38



**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Yes (Y)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Michael'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Adams'	System	23 Feb 2021 15:43:38



**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered '5251 S Green St'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Murray'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'UT'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered '84123'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 16:34:46
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'US'	(b) (4) System	23 Feb 2021 15:48:58

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Mar 2021 13:51:38
User entered '6'	System	11 Mar 2021 12:48:05
User entered '5'	System	10 Mar 2021 14:08:19
User entered '4'	System	03 Mar 2021 15:32:51
User entered '3'	System	02 Mar 2021 17:02:50
Signature has been broken.	System	25 Feb 2021 16:34:58
User entered '2'	System	25 Feb 2021 16:34:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered '1'	System	23 Feb 2021 15:48:58

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 10:22:50**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 18:50:37
User entered '03/Mar/2021 09:32'	System	03 Mar 2021 15:32:51

US3892042

Folder: SAE USA-US209-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:22:50

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:50:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Mar 2021 14:08:06
User entered 'I'	(b) (4), (b) (6)	03 Mar 2021 15:32:51



**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'USA-US209-2021-MRNA-1273-P301000003'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Yes (Y)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Yes (Y)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38



**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Michael'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Adams'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered '5251 S Green St'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Murray'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'UT'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered '84123'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 16:34:46
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'US'	(b) (4) System	23 Feb 2021 15:48:58

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Mar 2021 13:51:38
User entered '6'	System	11 Mar 2021 12:48:05
User entered '5'	System	10 Mar 2021 14:08:19
User entered '4'	System	03 Mar 2021 15:32:51
User entered '3'	System	02 Mar 2021 17:02:50
Signature has been broken.	System	25 Feb 2021 16:34:58
User entered '2'	System	25 Feb 2021 16:34:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered '1'	System	23 Feb 2021 15:48:58



**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form (5)**

**Generated On: 10 Jun 2021 10:22:50**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 18:50:42
User entered '10/Mar/2021 09:08'	System	10 Mar 2021 14:08:19

US3892042

Folder: SAE USA-US209-2021-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 10:22:50

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:50:45
User entered 'I'	(b) (4), (b) (6)	10 Mar 2021 14:08:19

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'USA-US209-2021-MRNA-1273-P301000003'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Yes (Y)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Yes (Y)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38



**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Michael'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Adams'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered '5251 S Green St'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Murray'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'UT'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered '84123'	System	23 Feb 2021 15:43:38



**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 16:34:46
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'US'	(b) (4) System	23 Feb 2021 15:48:58

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Mar 2021 13:51:38
User entered '6'	System	11 Mar 2021 12:48:05
User entered '5'	System	10 Mar 2021 14:08:19
User entered '4'	System	03 Mar 2021 15:32:51
User entered '3'	System	02 Mar 2021 17:02:50
Signature has been broken.	System	25 Feb 2021 16:34:58
User entered '2'	System	25 Feb 2021 16:34:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered '1'	System	23 Feb 2021 15:48:58

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form (6)**

**Generated On: 10 Jun 2021 10:22:50**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 18:50:49
User entered '11/Mar/2021 07:48'	System	11 Mar 2021 12:48:05

US3892042

Folder: SAE USA-US209-2021-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 10:22:50

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 18:50:51
User entered 'I'	(b) (4), (b) (6)	11 Mar 2021 12:48:05

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'USA-US209-2021-MRNA-1273-P301000003'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Yes (Y)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38



**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Yes (Y)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'No (N)'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Michael'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Adams'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered '5251 S Green St'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'Murray'	System	23 Feb 2021 15:43:38



**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered 'UT'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:44:02
User entered '84123'	System	23 Feb 2021 15:43:38

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:52:10
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 16:34:46
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
User entered 'US'	(b) (4) System	23 Feb 2021 15:48:58

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:22:50**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Mar 2021 13:51:38
User entered '6'	System	11 Mar 2021 12:48:05
User entered '5'	System	10 Mar 2021 14:08:19
User entered '4'	System	03 Mar 2021 15:32:51
User entered '3'	System	02 Mar 2021 17:02:50
Signature has been broken.	System	25 Feb 2021 16:34:58
User entered '2'	System	25 Feb 2021 16:34:58
User signature succeeded.	Michael Adams (b) (4)	23 Feb 2021 18:29:01
	(b) (4)	
User entered '1'	System	23 Feb 2021 15:48:58

**US3892042**

**Folder: SAE USA-US209-2021-MRNA-1273-P301000003**

**Form: Safety Report Form (7)**

**Generated On: 10 Jun 2021 10:22:50**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Mar 2021 22:43:46
User entered '19/Mar/2021 09:51'	System	19 Mar 2021 13:51:38

US3892042

Folder: SAE USA-US209-2021-MRNA-1273-P301000003

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 10:22:50

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Michael Adams (b) (4)	12 Apr 2021 16:26:22
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	30 Mar 2021 22:43:46
User entered 'I'	(b) (4), (b) (6)	19 Mar 2021 13:51:38