

US3502142 (Prod: University of Colorado Hospital)

Generated By: KC Joubran

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US3502142

Form: Participant Creation

Data signed: (b) (4) 16 Feb 2021 15:50:04

Generated On: 10 Jun 2021 07:57:35

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Participant ID

US3502142

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

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US3502142

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

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

US3502142

Folder: Screening

Form: Demographics

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

Date of Birth (MMM yyyy)	(b) (6) 1974
Age	45
Age Units	YEARS
Age (Derived)	45
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3502142

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

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

US3502142

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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US3502142

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

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Were any significant conditions reported?

Yes ☒

No ☐

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US3502142

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

Condition	HOT FLASHES
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



US3502142

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

Condition	PENICILLIN ALLERGY
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

US3502142

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

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

US3502142

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

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

US3502142

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	11 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	09:08 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 09:08
Height ( <i>xxx.x</i> )	167.6 cm
Weight ( <i>xxx.x</i> )	166.0 lb
BMI ( <i>xxx.x</i> )	26.86194 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)	

US3502142

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 SEP 2020

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

US3502142

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

Date of assessment (*dd MMM yyyy*) 11 SEP 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

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

If Surgically sterile, date of surgery (*dd MMM yyyy*) UN UNK 2010

Date of surgery unknown False

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

Date of last menstruation unknown False

US3502142

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

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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

US3502142

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

<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>	



US3502142

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

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

US3502142

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

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

What was the participant's randomization number? 113312

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 ☒

US3502142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

Height	ND - Not Done
Weight	ND - Not Done

US3502142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	08:30 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 08:30
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3502142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 SEP 2020
Time of assessment (00:00-23:59)	09:39 (24 HR)
Vital Signs Date and Time (derived)	11 SEP 2020 09:39
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3502142

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

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.*

US3502142

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

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

Treatment Date and Time (derived) 11 SEP 2020 09:09

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

US3502142

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 SEP 2020
Collection time (00:00-23:59)	08:58 (24 HR)
Collection date and time (derived)	11 SEP 2020 08:58



US3502142

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

Collection date (dd MMM yyyy)			11 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:03	11 SEP 2020 09:03
Nasopharyngeal Swab 2	No		

US3502142

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3502142

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:57:35

**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

95.0 °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 11 SEP 2020 09:29

PC Open Date & Time 11 SEP 2020 09:29

PC Close Date & Time 11 SEP 2020 11:59

US3502142

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:57:35

**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

97.2 °F

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

Yes ☐  
No ☒

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

PC Time Stamp	11 SEP 2020 20:21
PC Open Date & Time	11 SEP 2020 12:54
PC Close Date & Time	12 SEP 2020 11:59

US3502142

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

12 SEP 2020 12:00

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3502142

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:57:35

**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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 05:38

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3502142

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:57:35

**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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 08:46

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3502142

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59



US3502142

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 12:00

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3502142

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:57:35

**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

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 17:23

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 09:30

PC Open Date & Time

11 SEP 2020 09:29

PC Close Date & Time

11 SEP 2020 11:59

US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:57:35

**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

11 SEP 2020 20:23

PC Open Date & Time

11 SEP 2020 12:54

PC Close Date & Time

12 SEP 2020 11:59

US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 12:01

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 05:39

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:57:35

**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

15 SEP 2020 08:46

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59



US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 12:00

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 17:23

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3502142

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:57:35

**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 ☐

US3502142

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:57:35

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 09:31
PC Open Date & Time	11 SEP 2020 09:29
PC Close Date & Time	11 SEP 2020 11:59

US3502142

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:57:35

**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 ☐

US3502142

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:57:35

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

No ☒

Yes ☐

PC Time stamp	11 SEP 2020 20:23
PC Open Date & Time	11 SEP 2020 12:54
PC Close Date & Time	12 SEP 2020 11:59

US3502142

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:57:35

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

46 of 2329

EAB) (1725)

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:57:35**

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



US3502142

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:57:35

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

48 of 2329

EAB) (1725)

US3502142

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:57:35

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 05:39
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3502142

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:57:35

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

50 of 2329

EAB) (1725)

US3502142

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:57:35

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 08:46
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3502142

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:57:35

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 ☐

US3502142

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:57:35

Yes ☐

PC Time stamp

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3502142

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:57:35

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 ☒

US3502142

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:57:35

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



US3502142

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:57:35

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 ☒

US3502142

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:57:35

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 17:23
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3502142

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3502142

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3502142

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3502142

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3502142

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3502142

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3502142

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3502142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

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)	06 OCT 2020
Time of assessment (00:00-23:59)	12:10 (24 HR)
Vital Signs Date and Time (derived)	06 OCT 2020 12:10
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	95 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3502142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

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)	06 OCT 2020
Time of assessment (00:00-23:59)	13:19 (24 HR)
Vital Signs Date and Time (derived)	06 OCT 2020 13:19
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3502142

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 OCT 2020

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

US3502142

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

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) 06 OCT 2020

What was the treatment time? (00:00-23:59) 12:49 (24 HR)

Treatment Date and Time (derived) 06 OCT 2020 12:49

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

US3502142

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	06 OCT 2020
Collection time (00:00-23:59)	12:35 (24 HR)
Collection date and time (derived)	06 OCT 2020 12:35

US3502142

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

Collection date (dd MMM yyyy)			06 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:43	06 OCT 2020 12:43
Nasopharyngeal Swab 2	No		

US3502142

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3502142

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:57:35

**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

95.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 OCT 2020 13:09

PC Open Date & Time

06 OCT 2020 13:09

PC Close Date & Time

06 OCT 2020 15:39

US3502142

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:57:35

**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	06 OCT 2020 16:34
PC Open Date & Time	06 OCT 2020 16:34
PC Close Date & Time	07 OCT 2020 11:59

US3502142

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:57:35

**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

97.1 °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 OCT 2020 20:40

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3502142

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 OCT 2020 18:40

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3502142

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 OCT 2020 14:02

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3502142

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3502142

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:57:35

**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

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 OCT 2020 12:00

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3502142

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:57:35

**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

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 OCT 2020 01:27

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59



US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 OCT 2020 13:10

PC Open Date & Time

06 OCT 2020 13:09

PC Close Date & Time

06 OCT 2020 15:39

US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:57:35

**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

06 OCT 2020 16:34

PC Open Date & Time

06 OCT 2020 16:34

PC Close Date & Time

07 OCT 2020 11:59

US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

07 OCT 2020 20:40

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

08 OCT 2020 18:41

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:57:35

**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

09 OCT 2020 14:03

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 OCT 2020 12:00

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 OCT 2020 01:27

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59



US3502142

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:57:35

**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 ☐

US3502142

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:57:35

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

No ☒

Yes ☐

PC Time stamp	06 OCT 2020 13:10
PC Open Date & Time	06 OCT 2020 13:09
PC Close Date & Time	06 OCT 2020 15:39

US3502142

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:57:35

**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 ☐

US3502142

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:57:35

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

No ☒

Yes ☐

PC Time stamp	06 OCT 2020 16:35
PC Open Date & Time	06 OCT 2020 16:34
PC Close Date & Time	07 OCT 2020 11:59

US3502142

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:57:35

**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 ☒

US3502142

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:57:35

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 20:40
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3502142

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:57:35

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

94 of 2329

EAB) (1725)

US3502142

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:57:35

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 18:41
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59



US3502142

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:57:35

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

96 of 2329

EAB) (1725)

US3502142

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:57:35

Yes <input type="checkbox"/>	
PC Time stamp	09 OCT 2020 14:03
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3502142

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:57:35

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

98 of 2329

US3502142

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:57:35

Yes ☐

PC Time stamp

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3502142

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:57:35

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

100 of 2329

EAB) (1725)

US3502142

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:57:35

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

US3502142

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:57:35

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

102 of 2329

EAB) (1725)

US3502142

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:57:35

Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 01:27
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59



US3502142

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 OCT 2020

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

Comments ATTEMPTED X3

*If Contact Not Made, please provide Comments*

US3502142

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3502142

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

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*

US3502142

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3502142

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3502142

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3502142

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3502142

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 15:50:06

Generated On: 10 Jun 2021 07:57:35

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 NOV 2020
Time of assessment (00:00-23:59)	12:29 (24 HR)
Vital Signs Date and Time (derived)	03 NOV 2020 12:29
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3502142

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

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.*

US3502142

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	3 NOV 2020
Collection time (00:00-23:59)	13:00 (24 HR)
Collection date and time (derived)	3 NOV 2020 13:00

US3502142

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3502142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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

Date and time of submission

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3502142

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°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"/>

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 NOV 2020 13:25:36
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59



US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 DEC 2020 12:15:24

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

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	09 DEC 2020 19:37:28
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

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	13 DEC 2020 16:30:22
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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

24 DEC 2020 11:59:44

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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

29 DEC 2020 12:00:30

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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

05 JAN 2021 21:14:02

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

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	12 JAN 2021 12:00:28
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 JAN 2021 12:01:28
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59



US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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

26 JAN 2021 12:01:07

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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

02 FEB 2021 17:31:43

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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

09 FEB 2021 12:01:34

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 FEB 2021 12:00:49

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

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

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Open Date & Time](#)

21 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

25 FEB 2021 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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

02 MAR 2021 20:40:30

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 MAR 2021 12:00:24

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59



US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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

17 MAR 2021 18:14:48

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 MAR 2021 12:00:26

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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

01 APR 2021 11:59:27

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 APR 2021 12:00:22

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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

14 APR 2021 18:12:57

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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

21 APR 2021 10:06:15

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 APR 2021 12:00:19

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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

02 MAY 2021 17:02:12

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59



US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 243

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 250

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

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

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

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

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

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

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 ☐

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Close Date & Time](#)

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20 MAY 2021 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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 ☐

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 264

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

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

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

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

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

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

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 ☐

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59



US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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°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 ☐

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 JUN 2021 23:59

US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 285

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

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

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

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

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

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

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

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

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Open Date & Time](#)

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27 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUL 2021 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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 ☐

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 JUL 2021 23:59

US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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 ☐

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

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"/>

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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



US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Close Date & Time](#)

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05 AUG 2021 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

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

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

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Open Date & Time](#)

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08 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 AUG 2021 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

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"/>

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	15 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 AUG 2021 23:59
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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

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

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59



US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Open Date & Time](#)

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29 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 SEP 2021 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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 ☐

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Close Date & Time](#)

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09 SEP 2021 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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 ☐

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 SEP 2021 23:59

US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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 ☐

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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

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

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

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

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Close Date & Time](#)

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21 OCT 2021 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

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"/>

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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 ☐

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	31 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 NOV 2021 23:59

US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Close Date & Time](#)

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11 NOV 2021 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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 ☐

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 NOV 2021 23:59



US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 439

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Open Date & Time](#)

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21 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 NOV 2021 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Open Date & Time](#)

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28 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 DEC 2021 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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 ☐

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	05 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	09 DEC 2021 23:59
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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

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="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"/>

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 DEC 2021 23:59



US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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 ☐

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

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

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Close Date & Time](#)

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06 JAN 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

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"/>

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

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"/>

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Close Date & Time](#)

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20 JAN 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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 ☐

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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 ☐

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Close Date & Time](#)

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03 FEB 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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 ☐

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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 ☐

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Close Date & Time](#)

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17 FEB 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

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"/>

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Close Date & Time](#)

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24 FEB 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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 ☐

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Close Date & Time](#)

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03 MAR 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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 ☐

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Close Date & Time](#)

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10 MAR 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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°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 ☐

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Close Date & Time](#)

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17 MAR 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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 ☐

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Close Date & Time](#)

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24 MAR 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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 ☐

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 MAR 2022 23:59

US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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 ☐

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Close Date & Time](#)

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07 APR 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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 ☐

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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°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 ☐

**US3502142**

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

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**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Close Date & Time](#)

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21 APR 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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 ☐

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Open Date & Time](#)

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24 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 APR 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

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="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"/>

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Open Date & Time](#)

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01 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 MAY 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

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"/>

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

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"/>

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Open Date & Time](#)

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15 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

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"/>

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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 ☐

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Open Date & Time](#)

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29 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 JUN 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

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"/>

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Close Date & Time](#)

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09 JUN 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Close Date & Time](#)

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16 JUN 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

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

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Open Date & Time](#)

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19 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 JUN 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Open Date & Time](#)

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26 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 JUN 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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 ☐

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Open Date & Time](#)

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03 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 JUL 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

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"/>

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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 ☐

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

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

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Open Date & Time](#)

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24 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 JUL 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

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

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Close Date & Time](#)

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04 AUG 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 698

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Open Date & Time](#)

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07 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	14 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 AUG 2022 23:59
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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

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

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

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Open Date & Time](#)

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21 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 AUG 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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 ☐

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Open Date & Time](#)

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28 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 SEP 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

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

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Open Date & Time](#)

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04 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 SEP 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

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="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"/>

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

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"/>

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Close Date & Time](#)

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22 SEP 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 SEP 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 SEP 2022 23:59
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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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 ☐

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Close Date & Time](#)

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06 OCT 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Open Date & Time](#)

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09 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 OCT 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

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"/>

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Close Date & Time](#)

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20 OCT 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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 ☐

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Open Date & Time](#)

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23 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 OCT 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**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 ☐

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Close Date & Time](#)

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03 NOV 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

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[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

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US3502142

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:57:35

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"/>

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 NOV 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 NOV 2022 23:59



**US3502142**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 10 Jun 2021 07:57:35**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		02 MAR 2021 20:40:40

US3502142

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3502142

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3502142

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

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

PT IN CLINIC FOR DECISION

VISIT 1/8/21

*If Contact Not Made, please provide Comments*

US3502142

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3502142

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:48:53

Generated On: 10 Jun 2021 07:57:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

PT IN CLINIC FOR DECISION

VISIT 2/5/21

*If Contact Not Made, please provide Comments*

US3502142

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3502142

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 21:07:21

Generated On: 10 Jun 2021 07:57:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

IN FOR OL DAY 57 3/9/21

*If Contact Not Made, please provide Comments*



US3502142

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 21:07:21

Generated On: 10 Jun 2021 07:57:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3502142

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 21:07:21

Generated On: 10 Jun 2021 07:57:35

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

Visit date (dd MMM yyyy)	30 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3502142

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 21:07:21

Generated On: 10 Jun 2021 07:57:35

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	30 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	11:55 (24 HR)
Vital Signs Date and Time (derived)	30 MAR 2021 11:55
Temperature ( <i>xxx.x</i> )	36.2 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse ( <i>xxx</i> )	86 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	87 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3502142

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 21:07:21

Generated On: 10 Jun 2021 07:57:35

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.*

US3502142

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 21:07:21

Generated On: 10 Jun 2021 07:57:35

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

Collection date (dd MMM yyyy)	30 MAR 2021
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Collection time (00:00-23:59)	12:15 (24 HR)
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Collection date and time (derived)	30 MAR 2021 12:15
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US3502142

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 21:07:21

Generated On: 10 Jun 2021 07:57:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3502142**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

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*

**US3502142**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:35**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag



**US3502142**

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

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 07:57:35**

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

**US3502142**

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

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

**Generated On: 10 Jun 2021 07:57:35**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3502142

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

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 15:50:04

Generated On: 10 Jun 2021 07:57:35

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

Visit date (dd MMM yyyy)	08 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>

Folder OID	UNBLND_DECIDE
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US3502142

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

Form: Unblinding

Data signed: (b) (4) 19 Mar 2021 19:43:48

Generated On: 10 Jun 2021 07:57:35

Date of updated informed consent ( <i>dd MMM yyyy</i> )	08 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	08 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3502142

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Feb 2021 15:50:04

Generated On: 10 Jun 2021 07:57:35

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	

US3502142

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 15:50:04

Generated On: 10 Jun 2021 07:57:35

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 JAN 2021
Time of assessment (00:00-23:59)	10:25 (24 HR)
Vital Signs Date and Time (derived)	08 JAN 2021 10:25
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3502142

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 15:50:04

Generated On: 10 Jun 2021 07:57:35

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/> No <input checked="" type="radio"/>
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 <input type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
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	

US3502142

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

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 15:50:04

Generated On: 10 Jun 2021 07:57:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 JAN 2021

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



US3502142

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

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 15:50:04

Generated On: 10 Jun 2021 07:57:35

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 08 JAN 2021

What was the treatment time? (00:00-23:59) 10:45 (24 HR)

Treatment Date and Time (derived) 08 JAN 2021 10:45

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

US3502142

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 21:48:53

Generated On: 10 Jun 2021 07:57:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	08 JAN 2021
Collection time (00:00-23:59)	10:35 (24 HR)
Collection date and time (derived)	08 JAN 2021 10:35

US3502142

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 21:48:53

Generated On: 10 Jun 2021 07:57:35

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	08 JAN 2021
Collection time (00:00 - 23:59)	10:30
Collection Date and Time (derived)	08 JAN 2021 10:30

US3502142

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

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:50:04

Generated On: 10 Jun 2021 07:57:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3502142

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3502142

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:50:05

Generated On: 10 Jun 2021 07:57:35

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3502142

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 15:50:04

Generated On: 10 Jun 2021 07:57:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3502142

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 15:50:04

Generated On: 10 Jun 2021 07:57:35

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 FEB 2021
Time of assessment (00:00-23:59)	09:20 (24 HR)
Vital Signs Date and Time (derived)	05 FEB 2021 09:20
Temperature (xxx.x)	96.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG



US3502142

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 15:50:04

Generated On: 10 Jun 2021 07:57:35

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 FEB 2021
Time of assessment (00:00-23:59)	10:02 (24 HR)
Vital Signs Date and Time (derived)	05 FEB 2021 10:02
Temperature (xxx.x)	96.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3502142

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 15:50:04

Generated On: 10 Jun 2021 07:57:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 FEB 2021

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

US3502142

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 15:50:04

Generated On: 10 Jun 2021 07:57:35

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 05 FEB 2021

What was the treatment time? (00:00-23:59) 09:29 (24 HR)

Treatment Date and Time (derived) 05 FEB 2021 09:29

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

US3502142

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:50:04

Generated On: 10 Jun 2021 07:57:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3502142

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 19:43:48

Generated On: 10 Jun 2021 07:57:35

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3502142

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 19:43:48

Generated On: 10 Jun 2021 07:57:35

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3502142

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 19:43:48

Generated On: 10 Jun 2021 07:57:35

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 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	OLD57

US3502142

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Mar 2021 19:43:48

Generated On: 10 Jun 2021 07:57:35

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	09 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	10:52 (24 HR)
Vital Signs Date and Time (derived)	09 MAR 2021 10:52
Temperature ( <i>xxx.x</i> )	35.9 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse ( <i>xxx</i> )	91 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	66 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3502142

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 19:43:48

Generated On: 10 Jun 2021 07:57:35

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 MAR 2021

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

US3502142

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Mar 2021 19:43:48

Generated On: 10 Jun 2021 07:57:35

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

09 MAR 2021

Collection time (00:00-23:59)

11:10 (24 HR)

Collection date and time (derived)

09 MAR 2021 11:10

US3502142

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Feb 2021 15:50:04

Generated On: 10 Jun 2021 07:57:35

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3502142

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 19:43:48

Generated On: 10 Jun 2021 07:57:35

AEID	USA-US080-2020-MRNA-1273-P30 1000002
Adverse event	MULTIPLE SCLEROSIS
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)	12 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	23 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	12 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	13 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

347 of 2329

US3502142

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 19:43:48

Generated On: 10 Jun 2021 07:57:35

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

US3502142

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 19:43:48

Generated On: 10 Jun 2021 07:57:35

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11/12/2020: DEVELOPED ACUTE  
NUMBNESS ON RIGHT FACE  
(FOREHEAD TO NECK ON  
RIGHT SIDE OF NECK), EARLY  
IN THE MORNING OF  
12-NOV-2020. SYMPTOMS  
IMPROVED AND UPON WAKING  
IN THE MORNING SYMPTOMS  
WERE RESOLVED. SHE WENT  
TO WORK AND AROUND  
10:00-11:00 AM SHE HAD  
RETURN OF SAME SYMPTOMS  
AND PRESENTED TO SAINT  
ANTHONY'S EMERGENCY  
DEPARTMENT FOR  
EVALUATION. MRI OF BRAIN  
BY VERBAL REPORT SHOWS A  
RIGHT SIDED BRAIN STEM  
LESION AND OTHER  
MULTIFOCAL WHITE MATTER  
LESIONS. ADMITTING  
DIAGNOSIS IS STROKE VERSUS  
DEMYLINATING PROCESS.  
11/13/2020 ADDENDUM: MRI  
WITH CONTRAST 11/12/2020  
SHOWS ENHANCING LESIONS  
IN LEFT FRONTAL LOBE, LEFT  
PARIETAL LOBE AND LEFT  
VENTRAL MEDULLA  
SATISFYING IMAGING  
REQUIREMENTS FOR MULTIPLE  
SCLEROSIS AND RECOMMEND  
TREATMENT WITH  
SOLUMEDROL. GIVEN THE  
ADDITIONAL INFORMATION I

US3502142

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 19:43:48

Generated On: 10 Jun 2021 07:57:35

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HAVE UPDATED THE ADVERSE  
EVENT TERM TO "MULTIPLE  
SCLEROSIS." GIVEN THAT THIS  
IS A DEMYLINATING PROCESS  
THAT OCCURRED 5 WEEKS  
AFTER THE SECOND DOSE OF  
INVESTIGATIONAL PRODUCT, I  
HAVE UPDATED RELATIONSHIP  
TO INVESTIGATIONAL  
PRODUCT AS "RELATED."

11/19/2020 ADDENDUM:

PARTICIPANT WAS  
EVALUATED BY NEUROLOGY  
CONSULT AT ROCKY  
MOUNTAIN MS CENTER ON  
11/18/2020. THE CONSULTING  
NEUROLOGIST BELIEVES THAT  
THE PARTICIPANT HAS HAD A  
FIRST CLINICAL ATTACK OF  
MS AND THT IT IS NOT  
RELATED TO STUDY  
TREATMENT. SINCE THE  
CONSULTING NEUROLOGIST  
BELIEVES THAT THE MS IS  
EXPLAINED MORE LIKELY BY  
OTHER CAUSES THAN BY THE  
VACCINE I HAVE CHANGED  
RELATIONSHIP TO IP AS "NOT  
RELATED."

11/23/2020: LUMBAR PUNCTURE  
WITH CSF INTERPRETATION.

INTERPRETATION:  
ISOELECTRIC  
FOCUSING/IMMUNOFIXATION  
REVEALS TWO OR MORE

US3502142

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 19:43:48

Generated On: 10 Jun 2021 07:57:35

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UNIQUE BANDS IN THE CSF  
BUT NO BANDS IN THE SERUM.  
C/W INTRATHECAL SYNTHESIS  
OF IMMUNOGLOBULIN AND  
CONSIDERED TO BE POSITIVE  
RESULT OF OLIGOCLONAL  
BANDS. OLIGOCLONAL BANDS  
ARE PRESENT IN ~95% OF PTS  
WITH MS BUT MAY BE  
PRESENT IN CSF OF OTHER  
NEURO DISEASE. INCREASED  
CONCENTRATIONS OF IGG  
IMPORTANT INDICATOR TO MS  
BUT COULD BE A/W WITH  
INCREASED PERMEABILITY OF  
BLOOD-CSF BARRIER.

---

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

---



US3502142

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Mar 2021 19:43:48

Generated On: 10 Jun 2021 07:57:35

AEID	
Adverse event	VITAMIN D DEFICIENCY
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

352 of 2329

US3502142

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 19 Mar 2021 19:43:48

Generated On: 10 Jun 2021 07:57:35

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" 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	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 16 Feb 2021 15:50:04

Generated On: 10 Jun 2021 07:57:35

---

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

Yes ☒

No ☐

---

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

---

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 21:07:21

Generated On: 10 Jun 2021 07:57:35

Name of Medication VENLAFAXINE

Prophylaxis Yes ☐  
No ☒

Indication HOT FLASHES

Dose per administration 37.5

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 ☐

PRODUCTION RELEASE (v12.003

355 of 2329

EAB) (1725)

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 21:07:21

Generated On: 10 Jun 2021 07:57:35

	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 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 21:07:21

Generated On: 10 Jun 2021 07:57:35

Name of Medication FLU VACCINE

Prophylaxis Yes ☒  
No ☐

Indication FLU PREVENTION

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 ☐

PRODUCTION RELEASE (v12.003

357 of 2329

EAB) (1725)

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 21:07:21

Generated On: 10 Jun 2021 07:57:35

	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)	26 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)		26 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"/>

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 21:07:21

Generated On: 10 Jun 2021 07:57:35

Name of Medication SOLUMEDROL

Prophylaxis Yes ☐  
No ☒

Indication MULTIPLE SCLEROSIS

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 ☐

PRODUCTION RELEASE (v12.003

359 of 2329

EAB) (1725)



US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 21:07:21

Generated On: 10 Jun 2021 07:57:35

	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)	12 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	13 NOV 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="checkbox"/>	

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 21:07:21

Generated On: 10 Jun 2021 07:57:35

Name of Medication SOLUMEDROL

Prophylaxis Yes ☐  
No ☒

Indication MULTIPLE SCLEROSIS

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

361 of 2329

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 21:07:21

Generated On: 10 Jun 2021 07:57:35

	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)		14 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 21:07:21

Generated On: 10 Jun 2021 07:57:35

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☒  
No ☐

Indication PREVENT STEROID INDUCED  
ULCERS

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003

363 of 2329

EAB) (1725)

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 21:07:21

Generated On: 10 Jun 2021 07:57:35

	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)	12 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 21:07:21

Generated On: 10 Jun 2021 07:57:35

Name of Medication ERGOCALCIFEROL

Prophylaxis Yes ☐  
No ☒

Indication VITAMIN D DEFICIENCY

Dose per administration 50000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

365 of 2329

EAB) (1725)

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 21:07:21

Generated On: 10 Jun 2021 07:57:35

	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)	12 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input checked="" type="radio"/>
	804	<input type="radio"/>

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 21:07:21

Generated On: 10 Jun 2021 07:57:35

Name of Medication VITAMIN D

Prophylaxis Yes ☐  
No ☒

Indication VITAMIN D DEFICIENCY

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 ☐

PRODUCTION RELEASE (v12.003

367 of 2329

EAB) (1725)



US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 21:07:21

Generated On: 10 Jun 2021 07:57:35

	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)	14 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 21:07:21

Generated On: 10 Jun 2021 07:57:35

Name of Medication CALCIUM

Prophylaxis Yes ☐  
No ☒

Indication VITAMIN D DEFICIENCY

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

369 of 2329

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 21:07:21

Generated On: 10 Jun 2021 07:57:35

	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)	14 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 21:07:21

Generated On: 10 Jun 2021 07:57:35

Name of Medication SHINGRIX (SECOND DOSE)

Prophylaxis Yes ☒  
No ☐

Indication SHINGLES PREVENTION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

371 of 2329

EAB) (1725)

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 21:07:21

Generated On: 10 Jun 2021 07:57:35

	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)	09 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	09 MAR 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"/>	

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 21:07:21

Generated On: 10 Jun 2021 07:57:35

Name of Medication SHINGRIX (FIRST DOSE)

Prophylaxis Yes ☒  
No ☐

Indication SHINGLES PREVENTION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

373 of 2329

EAB) (1725)

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 21:07:21

Generated On: 10 Jun 2021 07:57:35

	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)		14 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		14 DEC 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"/>

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 21:07:21

Generated On: 10 Jun 2021 07:57:35

Name of Medication VUMERITY

Prophylaxis Yes ☐  
No ☒

Indication MULTIPLE SCLEROSIS

Dose per administration 231

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

375 of 2329

EAB) (1725)



US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 21:07:21

Generated On: 10 Jun 2021 07:57:35

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	23 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3502142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Feb 2021 15:50:04

Generated On: 10 Jun 2021 07:57:35

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3502142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 08 Apr 2021 21:07:21

Generated On: 10 Jun 2021 07:57:35

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
12 NOV 2020	MRI ON BRAIN	Adverse Event	
23 NOV 2020	LUMBAR PUNCTURE	Adverse Event	

US3502142

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 07:57:35

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

US3502142

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 07:57:35

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 ☐

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 19 Mar 2021 19:43:48

Generated On: 10 Jun 2021 07:57:35

SAEID	USA-US080-2020-MRNA-1273-P301000002
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	THOMAS
Investigator's Last Name	CAMPBELL
Site Address: Street	
Site Address: City	
Site Address: State	CO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 19 Mar 2021 19:43:48

Generated On: 10 Jun 2021 07:57:35

SAEID	USA-US080-2020-MRNA-1273-P301000002
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	THOMAS
Investigator's Last Name	CAMPBELL
Site Address: Street	
Site Address: City	
Site Address: State	CO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	13/NOV/2020 10:39
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 19 Mar 2021 19:43:48

Generated On: 10 Jun 2021 07:57:35

SAEID	USA-US080-2020-MRNA-1273-P301000002
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	THOMAS
Investigator's Last Name	CAMPBELL
Site Address: Street	
Site Address: City	
Site Address: State	CO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	13/NOV/2020 11:45
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.	False



US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 19 Mar 2021 19:43:48

Generated On: 10 Jun 2021 07:57:35

SAEID	USA-US080-2020-MRNA-1273-P301000002
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	THOMAS
Investigator's Last Name	CAMPBELL
Site Address: Street	
Site Address: City	
Site Address: State	CO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	16/NOV/2020 09:26
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

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 19 Mar 2021 19:43:48

Generated On: 10 Jun 2021 07:57:35

SAEID	USA-US080-2020-MRNA-1273-P301000002
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	THOMAS
Investigator's Last Name	CAMPBELL
Site Address: Street	
Site Address: City	
Site Address: State	CO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	19/NOV/2020 13:14
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.	False

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Data signed: (b) (4) 19 Mar 2021 19:43:48

Generated On: 10 Jun 2021 07:57:35

SAEID	USA-US080-2020-MRNA-1273-P301000002
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	THOMAS
Investigator's Last Name	CAMPBELL
Site Address: Street	
Site Address: City	
Site Address: State	CO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	20/NOV/2020 14:52
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

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Data signed: (b) (4) 19 Mar 2021 19:43:48

Generated On: 10 Jun 2021 07:57:35

SAEID	USA-US080-2020-MRNA-1273-P301000002
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	THOMAS
Investigator's Last Name	CAMPBELL
Site Address: Street	
Site Address: City	
Site Address: State	CO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	24/NOV/2020 13:43
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

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Data signed: (b) (4) 19 Mar 2021 19:43:48

Generated On: 10 Jun 2021 07:57:35

SAEID	USA-US080-2020-MRNA-1273-P301000002
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	THOMAS
Investigator's Last Name	CAMPBELL
Site Address: Street	
Site Address: City	
Site Address: State	CO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	24/NOV/2020 10:01
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

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Data signed: (b) (4) 19 Mar 2021 19:43:48

Generated On: 10 Jun 2021 07:57:35

SAEID	USA-US080-2020-MRNA-1273-P301000002
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	THOMAS
Investigator's Last Name	CAMPBELL
Site Address: Street	
Site Address: City	
Site Address: State	CO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	25/NOV/2020 17:42
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

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form (9)

Data signed: (b) (4) 19 Mar 2021 19:43:48

Generated On: 10 Jun 2021 07:57:35

SAEID	USA-US080-2020-MRNA-1273-P301000002
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	THOMAS
Investigator's Last Name	CAMPBELL
Site Address: Street	
Site Address: City	
Site Address: State	CO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	27/NOV/2020 14:56
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

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form (10)

Data signed: (b) (4) 19 Mar 2021 19:43:48

Generated On: 10 Jun 2021 07:57:35

SAEID	USA-US080-2020-MRNA-1273-P301000002
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	THOMAS
Investigator's Last Name	CAMPBELL
Site Address: Street	
Site Address: City	
Site Address: State	CO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	14/DEC/2020 06:18
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



US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form (11)

Data signed: (b) (4) 19 Mar 2021 19:43:48

Generated On: 10 Jun 2021 07:57:35

SAEID	USA-US080-2020-MRNA-1273-P301000002
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	THOMAS
Investigator's Last Name	CAMPBELL
Site Address: Street	
Site Address: City	
Site Address: State	CO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	08/DEC/2020 12:54
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

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form (12)

Data signed: (b) (4) 19 Mar 2021 19:43:48

Generated On: 10 Jun 2021 07:57:35

SAEID	USA-US080-2020-MRNA-1273-P301000002
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	THOMAS
Investigator's Last Name	CAMPBELL
Site Address: Street	
Site Address: City	
Site Address: State	CO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	10
Date of submission (Pre-filled from custom function)	02/MAR/2021 09:42
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

US3502142 (Prod: University of Colorado Hospital)

**US3502142**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 07:57:35**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'US3502142'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 14:30:00

**US3502142**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:57:35**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	11 Sep 2020 14:35:45

**US3502142**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '11 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 14:30:03

**US3502142**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Clinic (Clinic)'	Suzanne Fiorillo (b) (4)	11 Sep 2020 14:35:45

**US3502142**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:57:35**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User entered 'SCRN'	System	11 Sep 2020 14:35:45



**US3502142**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:57:35**

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered (b) (6) 1974'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 14:30:05

**US3502142**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:57:35**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '45'	Suzanne Fiorillo (b) (4)	11 Sep 2020 14:36:00

**US3502142**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:57:35**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User entered 'YEARS'	System	11 Sep 2020 14:36:00

**US3502142**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:57:35**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User entered '45'	System	11 Sep 2020 14:36:15

**US3502142**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:57:35**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Female (F)'	Suzanne Fiorillo (b) (4)	11 Sep 2020 14:36:00

**US3502142**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:57:35**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Suzanne Fiorillo (b) (4)	11 Sep 2020 14:36:00

**US3502142**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:57:35**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '0'	Suzanne Fiorillo (b) (4)	11 Sep 2020 14:36:00

**US3502142**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:57:35**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'I'	Suzanne Fiorillo (b) (4)	11 Sep 2020 14:36:00



**US3502142**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:57:35**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '0'	Suzanne Fiorillo (b) (4)	11 Sep 2020 14:36:00

**US3502142**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:57:35**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '0'	Suzanne Fiorillo (b) (4)	11 Sep 2020 14:36:00

**US3502142**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:57:35**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '0'	Suzanne Fiorillo (b) (4)	11 Sep 2020 14:36:00

**US3502142**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:57:35**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '0'	Suzanne Fiorillo (b) (4)	11 Sep 2020 14:36:00

**US3502142**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:57:35**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	Suzanne Fiorillo (b) (4)	11 Sep 2020 14:36:00

**US3502142**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:57:35**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '0'	Suzanne Fiorillo (b) (4)	11 Sep 2020 14:36:00

**US3502142**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:57:35**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '0'	Suzanne Fiorillo (b) (4)	11 Sep 2020 14:36:00

US3502142

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:57:35

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '11 Sep 2020'	Suzanne Fiorillo (b) (4)	11 Sep 2020 14:36:15



**US3502142**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User entered 'Sep 2020'	System	11 Sep 2020 14:36:15

**US3502142**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User entered '2020'	System	11 Sep 2020 14:36:15

**US3502142**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:57:35**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Amendment 3 (3)'	Suzanne Fiorillo (b) (4)	11 Sep 2020 14:36:15

**US3502142**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	11 Sep 2020 14:36:15

**US3502142**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:57:35**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	Suzanne Fiorillo (b) (4)	11 Sep 2020 14:36:15

**US3502142**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:57:35**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	Suzanne Fiorillo (b) (4)	11 Sep 2020 14:36:15

**US3502142**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:57:35**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'No (N)'	Suzanne Fiorillo (b) (4)	11 Sep 2020 14:36:15

**US3502142**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:57:35**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 14:30:03



**US3502142**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:57:35**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User entered 'I'	System	11 Sep 2020 14:36:20

**US3502142**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	11 Sep 2020 14:36:20

**US3502142**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 10 Jun 2021 07:57:35**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:16:00

US3502142

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:57:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User coded data point as SOC: Vascular disorders, HLT: Vascular disorders NEC, HLT: Peripheral vascular disorders NEC, PT: Hot flush, LLT: Hot flashes - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 17:17:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 17:17:44
Data point term sent to Coder	System	15 Sep 2020 17:17:07
User entered 'Hot flashes'	(b) (4), (b) (6)	15 Sep 2020 17:16:33

**US3502142**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'UN UNK 2016'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:16:33

**US3502142**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:16:33

**US3502142**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:16:33

**US3502142**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:16:33



**US3502142**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:16:33

**US3502142**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User entered 'Jan 2016'	System	15 Sep 2020 17:16:33

**US3502142**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User entered '2016'	System	15 Sep 2020 17:16:33

**US3502142**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User entered empty.	System	15 Sep 2020 17:16:33

**US3502142**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User entered empty.	System	15 Sep 2020 17:16:33

US3502142

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:57:35

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Penicillin allergy - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 17:19:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Sep 2020 17:19:43
Data point term sent to Coder	System	15 Sep 2020 17:18:13
User entered 'Penicillin allergy'	(b) (4), (b) (6)	15 Sep 2020 17:17:24

**US3502142**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'UN UNK 1980'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:17:24

**US3502142**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 07:57:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:17:24



**US3502142**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 07:57:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:17:24

**US3502142**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:17:24

**US3502142**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 07:57:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:17:24

**US3502142**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User entered 'Jan 1980'	System	15 Sep 2020 17:17:24

**US3502142**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User entered '1980'	System	15 Sep 2020 17:17:24

**US3502142**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User entered empty.	System	15 Sep 2020 17:17:24

**US3502142**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User entered empty.	System	15 Sep 2020 17:17:24

US3502142

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:57:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Ovarian therapeutic procedures, PT: Oophorectomy, LLT: Oophorectomy - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 05:18:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Nov 2020 05:18:41
Data point term sent to Coder	System	13 Nov 2020 21:51:50
User entered 'oophorectomy'	Josie Marshall (b) (4)	13 Nov 2020 21:51:33



**US3502142**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'un UNK 2010'	Josie Marshall (b) (4)	13 Nov 2020 21:51:33

**US3502142**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 07:57:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '0'	Josie Marshall (b) (4)	13 Nov 2020 21:51:33

**US3502142**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 07:57:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'No (N)'	Josie Marshall (b) (4)	13 Nov 2020 21:51:33

**US3502142**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'un UNK 2010'	Josie Marshall (b) (4)	13 Nov 2020 21:51:33

**US3502142**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 07:57:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '0'	Josie Marshall (b) (4)	13 Nov 2020 21:51:33

**US3502142**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User entered 'Jan 2010'	System	13 Nov 2020 21:51:33

**US3502142**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User entered '2010'	System	13 Nov 2020 21:51:33

**US3502142**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User entered 'Jan 2010'	System	13 Nov 2020 21:51:33



**US3502142**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User entered '2010'	System	13 Nov 2020 21:51:33

US3502142

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:57:35

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User coded data point as SOC: Reproductive system and breast disorders, HLG: Uterine, pelvic and broad ligament disorders, HLT: Uterine disorders NEC, PT: Endometriosis, LLT: Endometriosis - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 21:53:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 21:53:35
Data point term sent to Coder	System	13 Nov 2020 21:53:03
User entered 'endometriosis'	Josie Marshall (b) (4)	13 Nov 2020 21:52:54

**US3502142**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'un UNK 2010'	Josie Marshall (b) (4)	13 Nov 2020 21:52:54

**US3502142**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 07:57:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '0'	Josie Marshall (b) (4)	13 Nov 2020 21:52:54

**US3502142**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 07:57:35**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'No (N)'	Josie Marshall (b) (4)	13 Nov 2020 21:52:54

**US3502142**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'un UNK 2010'	Josie Marshall (b) (4)	13 Nov 2020 21:52:54

**US3502142**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 07:57:35**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '0'	Josie Marshall (b) (4)	13 Nov 2020 21:52:54

**US3502142**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User entered 'Jan 2010'	System	13 Nov 2020 21:52:54



**US3502142**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User entered '2010'	System	13 Nov 2020 21:52:54

**US3502142**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User entered 'Jan 2010'	System	13 Nov 2020 21:52:54

**US3502142**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User entered '2010'	System	13 Nov 2020 21:52:54

**US3502142**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:18:43

**US3502142**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:18:43

**US3502142**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '09:08'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:18:43

**US3502142**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User entered '11 Sep 2020 09:08'	System	15 Sep 2020 17:18:43

**US3502142**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '167.6' cm	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:18:43
DataPoint set to visible.	System	11 Sep 2020 14:36:20



**US3502142**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '166.0' lb	(b) (4), (b) (6)	15 Sep 2020 17:18:43
DataPoint set to visible.	System	11 Sep 2020 14:36:20

**US3502142**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User entered '26.86194'	System	15 Sep 2020 17:18:43
DataPoint set to visible.	System	11 Sep 2020 14:36:20

**US3502142**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User entered 'kg/m2'	System	15 Sep 2020 17:18:43
DataPoint set to visible.	System	11 Sep 2020 14:36:20

**US3502142**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:18:43

**US3502142**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:18:43

**US3502142**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:18:43

**US3502142**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:18:43

**US3502142**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User entered 'bpm'	System	15 Sep 2020 17:18:43



**US3502142**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:18:43

**US3502142**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User entered 'breaths/min'	System	15 Sep 2020 17:18:43

**US3502142**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:18:43

**US3502142**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User entered 'mmHg'	System	15 Sep 2020 17:18:43

**US3502142**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:18:43

**US3502142**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User entered 'mmHg'	System	15 Sep 2020 17:18:43

**US3502142**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03

**US3502142**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03



**US3502142**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:57:35**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:18:58

**US3502142**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:57:35**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:18:58

**US3502142**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 07:57:35**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:19:26

**US3502142**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:19:26

US3502142

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:57:35

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User closed query 'Per DM CLR: Note, If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 12:05:57
Query 'Per DM CLR: Note, If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' answered with 'done' (Site from DM).	Josie Marshall (b) (4) (b) (4)	13 Nov 2020 21:54:42
User opened query 'Per DM CLR: Note, If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 02:41:24
User entered 'Surgically sterile (SURGICALLY STERILE)'	(b) (4), (b) (6)	15 Sep 2020 17:19:26

**US3502142**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 07:57:35**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:19:26

**US3502142**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:19:26

**US3502142**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 07:57:35**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:19:26



**US3502142**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:19:26

**US3502142**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 07:57:35**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:19:26

US3502142

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:20:25

**US3502142**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:20:25

US3502142

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:20:25

US3502142

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:20:25

US3502142

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:20:25

US3502142

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:20:25



US3502142

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:20:25

US3502142

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:20:25

US3502142

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:20:25

US3502142

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:20:25

US3502142

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:20:25

US3502142

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:35

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
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	15 Sep 2020 17:20:45
User entered 'No (N)' reason for change: Data Entry Error	System	15 Sep 2020 17:20:45
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	15 Sep 2020 17:20:25
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:20:25

US3502142

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:35

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:20:25

**US3502142**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 07:57:35**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:20:25



US3502142

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:35

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:20:25

US3502142

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:35

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 17:20:25

US3502142

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:35

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:20:25

US3502142

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:35

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 17:20:25

US3502142

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:57:35

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'I'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:20:25

**US3502142**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 07:57:35**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:20:25

**US3502142**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 07:57:35**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:12:03
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:20:25

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:57:35**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	11 Sep 2020 14:36:35



**US3502142**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '11 Sep 2020'	Suzanne Fiorillo (b) (4)	11 Sep 2020 14:36:35

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Clinic (Clinic)'	Suzanne Fiorillo (b) (4)	11 Sep 2020 14:36:35

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:57:35**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'VISIT1'	System	11 Sep 2020 14:36:35

US3502142

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '11 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 14:30:15

US3502142

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:57:35

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '113312'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 14:30:15

US3502142

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:57:35

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Sep 2020 14:30:15

US3502142

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:57:35

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'No (N)'	Suzanne Fiorillo (b) (4)	11 Sep 2020 14:36:46

US3502142

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:57:35

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'No (N)'	Suzanne Fiorillo (b) (4)	11 Sep 2020 14:36:46



**US3502142**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 07:57:35**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'No (N)'	Suzanne Fiorillo (b) (4)	11 Sep 2020 14:36:46

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 07:57:35**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'No (N)'	Suzanne Fiorillo (b) (4)	11 Sep 2020 14:36:46

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 07:57:35**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'No (N)'	Suzanne Fiorillo (b) (4)	11 Sep 2020 14:36:46

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 07:57:35**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:49:07
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 06:08:14
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:08:13

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 07:57:35**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:21:55

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 07:57:35**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:21:55

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 07:57:35**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:21:55

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 07:57:35**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:21:55



US3502142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:35

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	15 Sep 2020 17:21:55

US3502142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:21:55

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:21:55

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '08:30'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:21:55

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered '11 Sep 2020 08:30'	System	15 Sep 2020 17:21:55

US3502142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '97.7' F	(b) (4), (b) (6)	15 Sep 2020 17:21:55

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:21:55

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Forehead'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:21:55



**US3502142**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '85'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:21:55

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'bpm'	System	15 Sep 2020 17:21:55

US3502142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '14'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:21:55

US3502142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'breaths/min'	System	15 Sep 2020 17:21:55

US3502142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '114'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:21:55

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'mmHg'	System	15 Sep 2020 17:21:55

US3502142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '76'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:21:55

US3502142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:35

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'mmHg'	System	15 Sep 2020 17:21:55



**US3502142**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 07:57:35**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:21:55

US3502142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:57:35

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:21:55

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	15 Sep 2020 17:23:33

US3502142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:23:33

US3502142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:23:33

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '09:39'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:23:33

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered '11 Sep 2020 09:39'	System	15 Sep 2020 17:23:33

US3502142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '36.4' C	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:23:33



US3502142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:23:33

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Forehead'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:23:33

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '67'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:23:33

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'bpm'	System	15 Sep 2020 17:23:33

US3502142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '16'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:23:33

US3502142

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'breaths/min'	System	15 Sep 2020 17:23:33

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '130'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:23:33

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'mmHg'	System	15 Sep 2020 17:23:33



**US3502142**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '77'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:23:33

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'mmHg'	System	15 Sep 2020 17:23:33

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:57:35**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:23:41

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:57:35**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:23:41

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:57:35**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	11 Sep 2020 15:11:36

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:57:35**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	Suzanne Fiorillo (b) (4)	11 Sep 2020 15:11:36

US3502142

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	Suzanne Fiorillo (b) (4)	11 Sep 2020 15:11:36

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:57:35**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'MRNA-1273 OR PLACEBO'	System	11 Sep 2020 15:11:36



US3502142

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:57:35

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '11 Sep 2020'	Suzanne Fiorillo (b) (4)	11 Sep 2020 15:11:36

US3502142

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:57:35

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '09:09'	Suzanne Fiorillo (b) (4)	11 Sep 2020 15:11:36

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:57:35**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered '11 Sep 2020 09:09'	System	11 Sep 2020 15:11:36

US3502142

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:57:35

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Left Arm (LEFT ARM)'	Suzanne Fiorillo (b) (4)	11 Sep 2020 15:11:36

US3502142

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:57:35

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'ONCE'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:57:35**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'INTRAMUSCULAR'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:57:35**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:24:09

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:57:35**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:24:09



**US3502142**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:57:35**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '08:58'	(b) (4), (b) (6)	15 Sep 2020 17:24:09

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:57:35**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered '11 Sep 2020 08:58'	System	15 Sep 2020 17:24:09

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 07:57:35**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:24:30

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	15 Sep 2020 17:24:30

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:24:30

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 07:57:35**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '09:03'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:24:30

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered '11 Sep 2020 09:03'	System	15 Sep 2020 17:24:30

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	15 Sep 2020 17:24:30



**US3502142**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:24:30

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 17:24:30

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered empty.	System	15 Sep 2020 17:24:30

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:35**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 17:24:39

**US3502142**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'I'	System	15 Sep 2020 17:24:39

US3502142

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	11 Sep 2020 15:11:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 07:57:35**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-11T09:29:34', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'b9e1f5c5-73b6-4d48-b3f2-d5433350e47b' User entered 'Yes (Y)'	System	11 Sep 2020 15:30:00
	System	11 Sep 2020 15:30:00

US3502142

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:57:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-11T09:29:42', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'b9e1f5c5-73b6-4d48-b3f2-d5433350e47b' User entered '95.0'	System	11 Sep 2020 15:30:00
	System	11 Sep 2020 15:30:00



US3502142

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-11T09:29:47', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'b9e1f5c5-73b6-4d48-b3f2-d5433350e47b'	System	11 Sep 2020 15:30:00
User entered 'No (N)'	System	11 Sep 2020 15:30:00

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-11T09:29:55', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'b9e1f5c5-73b6-4d48-b3f2-d5433350e47b' User entered '11 Sep 2020 09:29'	System	11 Sep 2020 15:30:00
	System	11 Sep 2020 15:30:00

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '11 Sep 2020 09:29'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '11 Sep 2020 11:59'	System	11 Sep 2020 15:11:36

US3502142

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	11 Sep 2020 15:11:36
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 07:57:35**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-11T20:21:32', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '7a037a35-dcc0-4586-af4f-0f9550699000' User entered 'Yes (Y)'	System	12 Sep 2020 02:29:34
	System	12 Sep 2020 02:29:34

US3502142

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:57:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-11T20:21:43', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '7a037a35-dcc0-4586-af4f-0f9550699000' User entered '97.2'	System	12 Sep 2020 02:29:34
	System	12 Sep 2020 02:29:34

US3502142

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-11T20:21:49', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '7a037a35-dcc0-4586-af4f-0f9550699000'	System	12 Sep 2020 02:29:34
User entered 'No (N)'	System	12 Sep 2020 02:29:34



**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-11T20:21:58', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '7a037a35-dcc0-4586-af4f-0f9550699000'	System	12 Sep 2020 02:29:34
User entered '11 Sep 2020 20:21'	System	12 Sep 2020 02:29:34

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '11 Sep 2020 12:54'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	11 Sep 2020 15:11:36
User entered 'Day 2'	System	11 Sep 2020 15:11:36

US3502142

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:57:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-12T12:00:39', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '40822ea2-fae8-4fbd-8de9-d25e6dfea6d5' User entered 'Yes (Y)'	System	12 Sep 2020 18:00:57
	System	12 Sep 2020 18:00:57

US3502142

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:57:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-12T12:00:45', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '40822ea2-fae8-4fbd-8de9-d25e6dfea6d5' User entered '98.0'	System	12 Sep 2020 18:00:57
	System	12 Sep 2020 18:00:57

US3502142

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-12T12:00:48', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '40822ea2-fae8-4fbd-8de9-d25e6dfea6d5'	System	12 Sep 2020 18:00:57
User entered 'No (N)'	System	12 Sep 2020 18:00:57

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-12T12:00:51', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '40822ea2-fae8-4fbd-8de9-d25e6dfea6d5'	System	12 Sep 2020 18:00:57
User entered '12 Sep 2020 12:00'	System	12 Sep 2020 18:00:57



**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 15:11:36

US3502142

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	11 Sep 2020 15:11:36
User entered 'Day 3'	System	11 Sep 2020 15:11:36

US3502142

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:57:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-14T05:38:29', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'abaa81f8-8dba-451e-8f76-57177026f8bb' User entered 'Yes (Y)'	System	14 Sep 2020 11:38:48
	System	14 Sep 2020 11:38:48

US3502142

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:57:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-14T05:38:36', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'abaa81f8-8dba-451e-8f76-57177026f8bb' User entered '97.7'	System	14 Sep 2020 11:38:48
	System	14 Sep 2020 11:38:48

US3502142

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-14T05:38:39', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'abaa81f8-8dba-451e-8f76-57177026f8bb'	System	14 Sep 2020 11:38:48
User entered 'No (N)'	System	14 Sep 2020 11:38:48

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-14T05:38:45', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'abaa81f8-8dba-451e-8f76-57177026f8bb' User entered '14 Sep 2020 05:38'	System	14 Sep 2020 11:38:48
	System	14 Sep 2020 11:38:48

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 15:11:36



**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	11 Sep 2020 15:11:36
User entered 'Day 4'	System	11 Sep 2020 15:11:36

US3502142

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:57:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-15T08:45:52', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '5fcf9a44-2122-45ad-8d2e-ec4f1f999541' User entered 'Yes (Y)'	System	15 Sep 2020 14:46:07
	System	15 Sep 2020 14:46:07

US3502142

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:57:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-15T08:45:59', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '5fcf9a44-2122-45ad-8d2e-ec4f1f999541' User entered '97.7'	System	15 Sep 2020 14:46:07
	System	15 Sep 2020 14:46:07

US3502142

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-15T08:46:02', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '5fcf9a44-2122-45ad-8d2e-ec4f1f999541'	System	15 Sep 2020 14:46:07
User entered 'No (N)'	System	15 Sep 2020 14:46:07

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-15T08:46:04', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '5fcf9a44-2122-45ad-8d2e-ec4f1f999541' User entered '15 Sep 2020 08:46'	System	15 Sep 2020 14:46:07
	System	15 Sep 2020 14:46:07

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 15:11:36



US3502142

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	11 Sep 2020 15:11:36
User entered 'Day 5'	System	11 Sep 2020 15:11:36

US3502142

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:57:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06

US3502142

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:57:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06

US3502142

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06

US3502142

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06

US3502142

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:57:35

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 15:11:36



**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	11 Sep 2020 15:11:36
User entered 'Day 6'	System	11 Sep 2020 15:11:36

US3502142

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:57:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-16T12:00:17', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'a9c95675-ed74-472d-9192-49a1e9f3a764' User entered 'Yes (Y)'	System	16 Sep 2020 18:00:35
	System	16 Sep 2020 18:00:35

US3502142

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:57:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-16T12:00:23', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'a9c95675-ed74-472d-9192-49a1e9f3a764' User entered '98.5'	System	16 Sep 2020 18:00:35
	System	16 Sep 2020 18:00:35

US3502142

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-16T12:00:27', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'a9c95675-ed74-472d-9192-49a1e9f3a764'	System	16 Sep 2020 18:00:35
User entered 'No (N)'	System	16 Sep 2020 18:00:35

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-16T12:00:30', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'a9c95675-ed74-472d-9192-49a1e9f3a764'	System	16 Sep 2020 18:00:35
User entered '16 Sep 2020 12:00'	System	16 Sep 2020 18:00:35

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 15:11:36



**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	11 Sep 2020 15:11:36
User entered 'Day 7'	System	11 Sep 2020 15:11:36

US3502142

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:57:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-17T17:23:06', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'ef16ac99-cfd1-4393-a594-b3c96a365a4a' User entered 'Yes (Y)'	System	17 Sep 2020 23:23:24
	System	17 Sep 2020 23:23:24

US3502142

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:57:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-17T17:23:11', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'ef16ac99-cfd1-4393-a594-b3c96a365a4a' User entered '96.7'	System	17 Sep 2020 23:23:24
	System	17 Sep 2020 23:23:24

US3502142

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-17T17:23:16', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'ef16ac99-cfd1-4393-a594-b3c96a365a4a'	System	17 Sep 2020 23:23:24
User entered 'No (N)'	System	17 Sep 2020 23:23:24

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-17T17:23:20', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'ef16ac99-cfd1-4393-a594-b3c96a365a4a'	System	17 Sep 2020 23:23:24
User entered '17 Sep 2020 17:23'	System	17 Sep 2020 23:23:24

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 15:11:36

US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	11 Sep 2020 15:11:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 15:11:36



US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-11T09:30:11', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '90490799-1a77-4f4f-9d4f-8125b60630f3'	System	11 Sep 2020 15:30:33
User entered 'None (1)'	System	11 Sep 2020 15:30:33

US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:57:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-11T09:30:15', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '90490799-1a77-4f4f-9d4f-8125b60630f3' User entered 'No (N)'	System	11 Sep 2020 15:30:33
	System	11 Sep 2020 15:30:33

US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-11T09:30:18', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '90490799-1a77-4f4f-9d4f-8125b60630f3' User entered 'No (N)'	System	11 Sep 2020 15:30:33
	System	11 Sep 2020 15:30:33

US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-11T09:30:25', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '90490799-1a77-4f4f-9d4f-8125b60630f3' User entered 'None (1)'	System	11 Sep 2020 15:30:33
	System	11 Sep 2020 15:30:33

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-11T09:30:30', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '90490799-1a77-4f4f-9d4f-8125b60630f3'	System	11 Sep 2020 15:30:33
User entered '11 Sep 2020 09:30'	System	11 Sep 2020 15:30:33

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '11 Sep 2020 09:29'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '11 Sep 2020 11:59'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	11 Sep 2020 15:11:36
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 15:11:36



US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-11T20:22:38', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'b6c4b544-6fbd-475f-89b6-d406d287ea00'	System	12 Sep 2020 02:26:20
User entered 'None (1)'	System	12 Sep 2020 02:26:20

US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:57:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-11T20:23:01', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'b6c4b544-6fbd-475f-89b6-d406d287ea00'	System	12 Sep 2020 02:26:20
User entered 'No (N)'	System	12 Sep 2020 02:26:20

US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-11T20:23:07', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'b6c4b544-6fbd-475f-89b6-d406d287ea00'	System	12 Sep 2020 02:26:20
User entered 'No (N)'	System	12 Sep 2020 02:26:20

US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-11T20:23:16', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'b6c4b544-6fbd-475f-89b6-d406d287ea00'	System	12 Sep 2020 02:26:20
User entered 'None (1)'	System	12 Sep 2020 02:26:20

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-11T20:23:24', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'b6c4b544-6fbd-475f-89b6-d406d287ea00' User entered '11 Sep 2020 20:23'	System	12 Sep 2020 02:26:20
	System	12 Sep 2020 02:26:20

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '11 Sep 2020 12:54'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 15:11:36

US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	11 Sep 2020 15:11:36
User entered 'Day 2'	System	11 Sep 2020 15:11:36



US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-12T12:00:57', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'c1789d0f-c379-4562-b585-6cf6a5d354bb' User entered 'None (1)'	System	12 Sep 2020 18:01:09
	System	12 Sep 2020 18:01:09

US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:57:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-12T12:01:00', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'c1789d0f-c379-4562-b585-6cf6a5d354bb' User entered 'No (N)'	System	12 Sep 2020 18:01:09
	System	12 Sep 2020 18:01:09

US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-12T12:01:02', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'c1789d0f-c379-4562-b585-6cf6a5d354bb'	System	12 Sep 2020 18:01:09
User entered 'No (N)'	System	12 Sep 2020 18:01:09

US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-12T12:01:05', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'c1789d0f-c379-4562-b585-6cf6a5d354bb' User entered 'None (1)'	System	12 Sep 2020 18:01:09
	System	12 Sep 2020 18:01:09

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-12T12:01:08', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'c1789d0f-c379-4562-b585-6cf6a5d354bb' User entered '12 Sep 2020 12:01'	System	12 Sep 2020 18:01:09
	System	12 Sep 2020 18:01:09

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 15:11:36

US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	11 Sep 2020 15:11:36
User entered 'Day 3'	System	11 Sep 2020 15:11:36



US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-14T05:38:51', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'a72f13a6-2c9b-4dd4-ac96-91ca14c6628b' User entered 'None (1)'	System	14 Sep 2020 11:39:09
	System	14 Sep 2020 11:39:09

US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:57:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-14T05:38:54', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'a72f13a6-2c9b-4dd4-ac96-91ca14c6628b' User entered 'No (N)'	System	14 Sep 2020 11:39:09
	System	14 Sep 2020 11:39:09

US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-14T05:38:56', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'a72f13a6-2c9b-4dd4-ac96-91ca14c6628b' User entered 'No (N)'	System	14 Sep 2020 11:39:09
	System	14 Sep 2020 11:39:09

US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-14T05:38:59', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'a72f13a6-2c9b-4dd4-ac96-91ca14c6628b' User entered 'None (1)'	System	14 Sep 2020 11:39:09
	System	14 Sep 2020 11:39:09

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-14T05:39:04', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'a72f13a6-2c9b-4dd4-ac96-91ca14c6628b' User entered '14 Sep 2020 05:39'	System	14 Sep 2020 11:39:09
	System	14 Sep 2020 11:39:09

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	11 Sep 2020 15:11:36
User entered 'Day 4'	System	11 Sep 2020 15:11:36



US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-15T08:46:08', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '2721a36b-0ceb-4f09-9f32-61b7f48cb655'	System	15 Sep 2020 14:46:21
User entered 'None (1)'	System	15 Sep 2020 14:46:21

US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:57:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-15T08:46:11', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '2721a36b-0ceb-4f09-9f32-61b7f48cb655'	System	15 Sep 2020 14:46:21
User entered 'No (N)'	System	15 Sep 2020 14:46:21

US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-15T08:46:14', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '2721a36b-0ceb-4f09-9f32-61b7f48cb655'	System	15 Sep 2020 14:46:21
User entered 'No (N)'	System	15 Sep 2020 14:46:21

US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-15T08:46:16', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '2721a36b-0ceb-4f09-9f32-61b7f48cb655'	System	15 Sep 2020 14:46:21
User entered 'None (1)'	System	15 Sep 2020 14:46:21

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-15T08:46:19', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '2721a36b-0ceb-4f09-9f32-61b7f48cb655'	System	15 Sep 2020 14:46:21
User entered '15 Sep 2020 08:46'	System	15 Sep 2020 14:46:21

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	11 Sep 2020 15:11:36
User entered 'Day 5'	System	11 Sep 2020 15:11:36



US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06

US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:57:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06

US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06

US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06

US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06

US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 15:11:36



**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	11 Sep 2020 15:11:36
User entered 'Day 6'	System	11 Sep 2020 15:11:36

US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-16T12:00:33', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'b0fb3c5f-e54a-4ba2-b175-1b3b59f059f5'	System	16 Sep 2020 18:00:46
User entered 'None (1)'	System	16 Sep 2020 18:00:46

US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:57:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-16T12:00:36', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'b0fb3c5f-e54a-4ba2-b175-1b3b59f059f5'	System	16 Sep 2020 18:00:46
User entered 'No (N)'	System	16 Sep 2020 18:00:46

US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-16T12:00:37', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'b0fb3c5f-e54a-4ba2-b175-1b3b59f059f5' User entered 'No (N)'	System	16 Sep 2020 18:00:46
	System	16 Sep 2020 18:00:46

US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-16T12:00:38', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'b0fb3c5f-e54a-4ba2-b175-1b3b59f059f5' User entered 'None (1)'	System	16 Sep 2020 18:00:46
	System	16 Sep 2020 18:00:46

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-16T12:00:41', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'b0fb3c5f-e54a-4ba2-b175-1b3b59f059f5'	System	16 Sep 2020 18:00:46
User entered '16 Sep 2020 12:00'	System	16 Sep 2020 18:00:46

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 15:11:36



**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	11 Sep 2020 15:11:36
User entered 'Day 7'	System	11 Sep 2020 15:11:36

US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-17T17:23:25', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'ba938eb8-a9a9-4776-b219-b35388834568'	System	17 Sep 2020 23:23:37
User entered 'None (1)'	System	17 Sep 2020 23:23:37

US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:57:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-17T17:23:26', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'ba938eb8-a9a9-4776-b219-b35388834568'	System	17 Sep 2020 23:23:37
User entered 'No (N)'	System	17 Sep 2020 23:23:37

US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-17T17:23:28', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'ba938eb8-a9a9-4776-b219-b35388834568' User entered 'No (N)'	System	17 Sep 2020 23:23:37
	System	17 Sep 2020 23:23:37

US3502142

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-17T17:23:30', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'ba938eb8-a9a9-4776-b219-b35388834568'	System	17 Sep 2020 23:23:37
User entered 'None (1)'	System	17 Sep 2020 23:23:37

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-17T17:23:34', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'ba938eb8-a9a9-4776-b219-b35388834568' User entered '17 Sep 2020 17:23'	System	17 Sep 2020 23:23:37
	System	17 Sep 2020 23:23:37

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 15:11:36



**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	11 Sep 2020 15:11:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:57:35**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-11T09:30:44', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '20dad9b4-3221-4fb1-88e3-69734b32da4e' User entered 'None (0)'	System	11 Sep 2020 15:31:08
	System	11 Sep 2020 15:31:08

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:57:35**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-11T09:30:47', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '20dad9b4-3221-4fb1-88e3-69734b32da4e' User entered 'None (0)'	System	11 Sep 2020 15:31:08
	System	11 Sep 2020 15:31:08

US3502142

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:57:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-11T09:30:49', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '20dad9b4-3221-4fb1-88e3-69734b32da4e' User entered 'None (0)'	System	11 Sep 2020 15:31:08
	System	11 Sep 2020 15:31:08

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:57:35**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-11T09:30:52', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '20dad9b4-3221-4fb1-88e3-69734b32da4e' User entered 'None (0)'	System	11 Sep 2020 15:31:08
	System	11 Sep 2020 15:31:08

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:57:35**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-11T09:30:54', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '20dad9b4-3221-4fb1-88e3-69734b32da4e' User entered 'None (0)'	System	11 Sep 2020 15:31:08
	System	11 Sep 2020 15:31:08

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:57:35**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-11T09:30:56', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '20dad9b4-3221-4fb1-88e3-69734b32da4e' User entered 'None (0)'	System	11 Sep 2020 15:31:08
	System	11 Sep 2020 15:31:08



US3502142

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-11T09:31:01', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '20dad9b4-3221-4fb1-88e3-69734b32da4e' User entered 'No (N)'	System	11 Sep 2020 15:31:08
	System	11 Sep 2020 15:31:08

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-11T09:31:05', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '20dad9b4-3221-4fb1-88e3-69734b32da4e' User entered '11 Sep 2020 09:31'	System	11 Sep 2020 15:31:08
	System	11 Sep 2020 15:31:08

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '11 Sep 2020 09:29'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '11 Sep 2020 11:59'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	11 Sep 2020 15:11:36
User entered 'Day 1, after vaccination (at home)'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:57:35**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-11T20:23:36', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'd35ca8bf-5005-47a9-a370-a5b09c7ec8df' User entered 'No interference with activity (1)'	System	12 Sep 2020 02:26:26
	System	12 Sep 2020 02:26:26

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:57:35**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-11T20:23:40', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'd35ca8bf-5005-47a9-a370-a5b09c7ec8df' User entered 'None (0)'	System	12 Sep 2020 02:26:26
	System	12 Sep 2020 02:26:26

US3502142

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:57:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-11T20:23:42', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'd35ca8bf-5005-47a9-a370-a5b09c7ec8df' User entered 'None (0)'	System	12 Sep 2020 02:26:26
	System	12 Sep 2020 02:26:26



**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:57:35**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-11T20:23:45', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'd35ca8bf-5005-47a9-a370-a5b09c7ec8df' User entered 'None (0)'	System	12 Sep 2020 02:26:26
	System	12 Sep 2020 02:26:26

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:57:35**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-11T20:23:48', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'd35ca8bf-5005-47a9-a370-a5b09c7ec8df' User entered 'None (0)'	System	12 Sep 2020 02:26:26
	System	12 Sep 2020 02:26:26

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:57:35**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-11T20:23:50', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'd35ca8bf-5005-47a9-a370-a5b09c7ec8df' User entered 'None (0)'	System	12 Sep 2020 02:26:26
	System	12 Sep 2020 02:26:26

US3502142

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-11T20:23:54', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'd35ca8bf-5005-47a9-a370-a5b09c7ec8df' User entered 'No (N)'	System	12 Sep 2020 02:26:26
	System	12 Sep 2020 02:26:26

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-11T20:23:57', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'd35ca8bf-5005-47a9-a370-a5b09c7ec8df' User entered '11 Sep 2020 20:23'	System	12 Sep 2020 02:26:26
	System	12 Sep 2020 02:26:26

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '11 Sep 2020 12:54'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '12 Sep 2020 11:59'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	11 Sep 2020 15:11:36
User entered 'Day 2'	System	11 Sep 2020 15:11:36



**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:57:35**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-12T12:01:16', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'fb3d2d22-a750-4f42-ae30-ca84939bf27e' User entered 'None (0)'	System	12 Sep 2020 18:01:37
	System	12 Sep 2020 18:01:37

US3502142

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:57:35

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-12T12:01:18', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'fb3d2d22-a750-4f42-ae30-ca84939bf27e' User entered 'None (0)'	System	12 Sep 2020 18:01:37
	System	12 Sep 2020 18:01:37

US3502142

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:57:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-12T12:01:20', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'fb3d2d22-a750-4f42-ae30-ca84939bf27e' User entered 'None (0)'	System	12 Sep 2020 18:01:37
	System	12 Sep 2020 18:01:37

US3502142

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:57:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-12T12:01:22', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'fb3d2d22-a750-4f42-ae30-ca84939bf27e' User entered 'None (0)'	System	12 Sep 2020 18:01:37
	System	12 Sep 2020 18:01:37

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:57:35**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-12T12:01:25', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'fb3d2d22-a750-4f42-ae30-ca84939bf27e' User entered 'None (0)'	System	12 Sep 2020 18:01:37
	System	12 Sep 2020 18:01:37

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:57:35**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-12T12:01:27', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'fb3d2d22-a750-4f42-ae30-ca84939bf27e' User entered 'None (0)'	System	12 Sep 2020 18:01:37
	System	12 Sep 2020 18:01:37

US3502142

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-12T12:01:29', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'fb3d2d22-a750-4f42-ae30-ca84939bf27e' User entered 'No (N)'	System	12 Sep 2020 18:01:37
	System	12 Sep 2020 18:01:37

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-12T12:01:33', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'fb3d2d22-a750-4f42-ae30-ca84939bf27e' User entered '12 Sep 2020 12:01'	System	12 Sep 2020 18:01:37
	System	12 Sep 2020 18:01:37



**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '12 Sep 2020 12:00'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '13 Sep 2020 11:59'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	11 Sep 2020 15:11:36
User entered 'Day 3'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:57:35**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-14T05:39:09', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '27d88eaa-9463-4697-93ed-48c7de7906bd' User entered 'None (0)'	System	14 Sep 2020 11:39:30
	System	14 Sep 2020 11:39:30

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:57:35**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-14T05:39:11', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '27d88eaa-9463-4697-93ed-48c7de7906bd' User entered 'None (0)'	System	14 Sep 2020 11:39:30
	System	14 Sep 2020 11:39:30

US3502142

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:57:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-14T05:39:13', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '27d88eaa-9463-4697-93ed-48c7de7906bd' User entered 'None (0)'	System	14 Sep 2020 11:39:30
	System	14 Sep 2020 11:39:30

US3502142

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:57:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-14T05:39:16', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '27d88eaa-9463-4697-93ed-48c7de7906bd' User entered 'None (0)'	System	14 Sep 2020 11:39:30
	System	14 Sep 2020 11:39:30

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:57:35**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-14T05:39:18', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '27d88eaa-9463-4697-93ed-48c7de7906bd' User entered 'None (0)'	System	14 Sep 2020 11:39:30
	System	14 Sep 2020 11:39:30



**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:57:35**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-14T05:39:20', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '27d88eaa-9463-4697-93ed-48c7de7906bd' User entered 'None (0)'	System	14 Sep 2020 11:39:30
	System	14 Sep 2020 11:39:30

US3502142

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-14T05:39:23', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '27d88eaa-9463-4697-93ed-48c7de7906bd' User entered 'No (N)'	System	14 Sep 2020 11:39:30
	System	14 Sep 2020 11:39:30

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-14T05:39:27', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '27d88eaa-9463-4697-93ed-48c7de7906bd' User entered '14 Sep 2020 05:39'	System	14 Sep 2020 11:39:30
	System	14 Sep 2020 11:39:30

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '13 Sep 2020 12:00'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '14 Sep 2020 11:59'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	11 Sep 2020 15:11:36
User entered 'Day 4'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:57:35**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-15T08:46:23', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '6b155139-bcdb-4567-92b4-23ec19e1293f' User entered 'None (0)'	System	15 Sep 2020 14:46:40
	System	15 Sep 2020 14:46:40

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:57:35**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-15T08:46:25', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '6b155139-bcdb-4567-92b4-23ec19e1293f' User entered 'None (0)'	System	15 Sep 2020 14:46:40
	System	15 Sep 2020 14:46:40



**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:57:35**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-15T08:46:26', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '6b155139-bcdb-4567-92b4-23ec19e1293f' User entered 'None (0)'	System	15 Sep 2020 14:46:40
	System	15 Sep 2020 14:46:40

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:57:35**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-15T08:46:28', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '6b155139-bcdb-4567-92b4-23ec19e1293f' User entered 'None (0)'	System	15 Sep 2020 14:46:40
	System	15 Sep 2020 14:46:40

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:57:35**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-15T08:46:30', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '6b155139-bcdb-4567-92b4-23ec19e1293f' User entered 'None (0)'	System	15 Sep 2020 14:46:40
	System	15 Sep 2020 14:46:40

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:57:35**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-15T08:46:32', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '6b155139-bcdb-4567-92b4-23ec19e1293f' User entered 'None (0)'	System	15 Sep 2020 14:46:40
	System	15 Sep 2020 14:46:40

US3502142

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-15T08:46:34', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '6b155139-bcdb-4567-92b4-23ec19e1293f' User entered 'No (N)'	System	15 Sep 2020 14:46:40
	System	15 Sep 2020 14:46:40

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-15T08:46:37', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '6b155139-bcdb-4567-92b4-23ec19e1293f' User entered '15 Sep 2020 08:46'	System	15 Sep 2020 14:46:40
	System	15 Sep 2020 14:46:40

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '14 Sep 2020 12:00'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '15 Sep 2020 11:59'	System	11 Sep 2020 15:11:36



**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	11 Sep 2020 15:11:36
User entered 'Day 5'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:57:35**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:57:35**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06

US3502142

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:57:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06

US3502142

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:57:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:57:35**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:57:35**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06

US3502142

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06



**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '15 Sep 2020 12:00'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '16 Sep 2020 11:59'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	11 Sep 2020 15:11:36
User entered 'Day 6'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:57:35**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-16T12:00:47', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '0924e690-b560-4757-a3c4-8d9c99a725e6' User entered 'None (0)'	System	16 Sep 2020 18:01:02
	System	16 Sep 2020 18:01:02

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:57:35**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-16T12:00:48', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '0924e690-b560-4757-a3c4-8d9c99a725e6' User entered 'None (0)'	System	16 Sep 2020 18:01:02
	System	16 Sep 2020 18:01:02

US3502142

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:57:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-16T12:00:49', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '0924e690-b560-4757-a3c4-8d9c99a725e6' User entered 'None (0)'	System	16 Sep 2020 18:01:02
	System	16 Sep 2020 18:01:02

US3502142

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:57:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-16T12:00:51', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '0924e690-b560-4757-a3c4-8d9c99a725e6' User entered 'None (0)'	System	16 Sep 2020 18:01:02
	System	16 Sep 2020 18:01:02



**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:57:35**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-16T12:00:53', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '0924e690-b560-4757-a3c4-8d9c99a725e6' User entered 'None (0)'	System	16 Sep 2020 18:01:02
	System	16 Sep 2020 18:01:02

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:57:35**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-16T12:00:54', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '0924e690-b560-4757-a3c4-8d9c99a725e6' User entered 'None (0)'	System	16 Sep 2020 18:01:02
	System	16 Sep 2020 18:01:02

US3502142

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-16T12:00:56', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '0924e690-b560-4757-a3c4-8d9c99a725e6' User entered 'No (N)'	System	16 Sep 2020 18:01:02
	System	16 Sep 2020 18:01:02

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-16T12:00:58', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '0924e690-b560-4757-a3c4-8d9c99a725e6' User entered '16 Sep 2020 12:00'	System	16 Sep 2020 18:01:02
	System	16 Sep 2020 18:01:02

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '16 Sep 2020 12:00'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '17 Sep 2020 11:59'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	11 Sep 2020 15:11:36
User entered 'Day 7'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:57:35**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-17T17:23:37', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '8012b082-95b4-4883-83cd-703f47486f78' User entered 'None (0)'	System	17 Sep 2020 23:23:55
	System	17 Sep 2020 23:23:55



US3502142

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:57:35

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-17T17:23:40', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '8012b082-95b4-4883-83cd-703f47486f78' User entered 'None (0)'	System	17 Sep 2020 23:23:55
	System	17 Sep 2020 23:23:55

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:57:35**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-17T17:23:41', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '8012b082-95b4-4883-83cd-703f47486f78' User entered 'None (0)'	System	17 Sep 2020 23:23:55
	System	17 Sep 2020 23:23:55

US3502142

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:57:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-17T17:23:43', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '8012b082-95b4-4883-83cd-703f47486f78' User entered 'None (0)'	System	17 Sep 2020 23:23:55
	System	17 Sep 2020 23:23:55

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:57:35**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-17T17:23:45', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '8012b082-95b4-4883-83cd-703f47486f78' User entered 'None (0)'	System	17 Sep 2020 23:23:55
	System	17 Sep 2020 23:23:55

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:57:35**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-17T17:23:47', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '8012b082-95b4-4883-83cd-703f47486f78' User entered 'None (0)'	System	17 Sep 2020 23:23:55
	System	17 Sep 2020 23:23:55

US3502142

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-17T17:23:49', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '8012b082-95b4-4883-83cd-703f47486f78' User entered 'No (N)'	System	17 Sep 2020 23:23:55
	System	17 Sep 2020 23:23:55

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-09-17T17:23:53', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '8012b082-95b4-4883-83cd-703f47486f78' User entered '17 Sep 2020 17:23'	System	17 Sep 2020 23:23:55
	System	17 Sep 2020 23:23:55

**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '17 Sep 2020 12:00'	System	11 Sep 2020 15:11:36



**US3502142**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '18 Sep 2020 11:59'	System	11 Sep 2020 15:11:36

**US3502142**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	Laurel Ware (b) (4)	22 Sep 2020 16:33:24

**US3502142**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '19 Sep 2020'	Laurel Ware (b) (4)	22 Sep 2020 16:33:24

**US3502142**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Contact Made (CONTACT MADE)'	Laurel Ware (b) (4)	22 Sep 2020 16:33:24

**US3502142**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	Laurel Ware (b) (4)	22 Sep 2020 16:33:24

**US3502142**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:35**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	Laurel Ware (b) (4)	22 Sep 2020 16:33:29

**US3502142**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'I'	System	22 Sep 2020 16:33:29

**US3502142**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	Laurel Ware (b) (4)	30 Sep 2020 17:32:43



**US3502142**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '28 Sep 2020'	Laurel Ware (b) (4)	30 Sep 2020 17:32:43

**US3502142**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Contact Made (CONTACT MADE)'	Laurel Ware (b) (4)	30 Sep 2020 17:32:43

**US3502142**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	Laurel Ware (b) (4)	30 Sep 2020 17:32:43

**US3502142**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:35**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	Laurel Ware (b) (4)	30 Sep 2020 17:33:04

**US3502142**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'I'	System	30 Sep 2020 17:33:04

**US3502142**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	Laurel Ware (b) (4)	02 Oct 2020 22:16:23

**US3502142**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '02 Oct 2020'	Laurel Ware (b) (4)	02 Oct 2020 22:16:23

**US3502142**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Contact Made (CONTACT MADE)'	Laurel Ware (b) (4)	02 Oct 2020 22:16:23



**US3502142**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	Laurel Ware (b) (4)	02 Oct 2020 22:16:23

**US3502142**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:35**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	Laurel Ware (b) (4)	02 Oct 2020 22:16:30

**US3502142**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'I'	System	02 Oct 2020 22:16:30

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:57:35**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Oct 2020 18:23:54

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '06 Oct 2020'	(b) (4), (b) (6)	06 Oct 2020 18:23:54

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 18:23:54

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:57:35**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'VISIT2'	System	06 Oct 2020 18:23:54

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	06 Oct 2020 21:50:52



**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:50:52

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '06 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:50:52

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '12:10'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:50:52

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered '06 Oct 2020 12:10'	System	06 Oct 2020 21:50:52

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '97.5' F	(b) (4), (b) (6)	06 Oct 2020 21:50:52

US3502142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:50:52

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Forehead'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:50:52

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '95'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:50:52



**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'bpm'	System	06 Oct 2020 21:50:52

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '14'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:50:52

US3502142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'breaths/min'	System	06 Oct 2020 21:50:52

US3502142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '112'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:50:52

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'mmHg'	System	06 Oct 2020 21:50:52

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '65'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:50:52

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'mmHg'	System	06 Oct 2020 21:50:52

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	06 Oct 2020 21:50:52



**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:50:52

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '06 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:50:52

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '13:19'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:50:52

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered '06 Oct 2020 13:19'	System	06 Oct 2020 21:50:52

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '98.0' F	(b) (4), (b) (6)	06 Oct 2020 21:50:52

US3502142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:50:52

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Forehead'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:50:52

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '86'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:50:52



**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'bpm'	System	06 Oct 2020 21:50:52

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '16'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:50:52

US3502142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:35

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'breaths/min'	System	06 Oct 2020 21:50:52

US3502142

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '128'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:50:52

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'mmHg'	System	06 Oct 2020 21:50:52

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '70'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:50:52

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'mmHg'	System	06 Oct 2020 21:50:52

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:57:35**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:51:07



**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:57:35**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '06 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:51:07

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:57:35**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 18:51:12

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:57:35**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 18:51:12

US3502142

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 18:51:12

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:57:35**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'MRNA-1273 OR PLACEBO'	System	06 Oct 2020 18:51:12

US3502142

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:35

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '06 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 18:51:12

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:57:35**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '12:49'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 18:51:12

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:57:35**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered '06 Oct 2020 12:49'	System	06 Oct 2020 18:51:12



**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:57:35**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 18:51:12

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:57:35**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'ONCE'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:57:35**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'INTRAMUSCULAR'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:57:35**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:51:22

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:57:35**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '06 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:51:22

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:57:35**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '12:35' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Oct 2020 21:51:34
User entered '12:49'	(b) (4), (b) (6)	06 Oct 2020 21:51:22

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:57:35**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered '06 Oct 2020 12:35'	System	06 Oct 2020 21:51:34
User entered '06 Oct 2020 12:49'	System	06 Oct 2020 21:51:22

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 07:57:35**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '06 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:51:47



US3502142

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:57:35

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 06OCT2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 12:54:50
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 06OCT2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 11:46:35
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	06 Oct 2020 21:51:47

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:51:47

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '12:43'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:51:47

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered '06 Oct 2020 12:43'	System	06 Oct 2020 21:51:47

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	06 Oct 2020 21:51:47

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:51:47

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 07:57:35**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:51:47

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered empty.	System	06 Oct 2020 21:51:47



**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:35**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 21:51:52

**US3502142**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'I'	System	06 Oct 2020 21:51:52

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	06 Oct 2020 18:51:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 18:51:12

US3502142

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:57:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-06T13:09:23', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '9cd2fc6b-26ea-4f6a-b0b5-9d0177fedf4d' User entered 'Yes (Y)'	System	06 Oct 2020 19:09:48
	System	06 Oct 2020 19:09:48

US3502142

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:57:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-06T13:09:28', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '9cd2fc6b-26ea-4f6a-b0b5-9d0177fedf4d' User entered '95.5'	System	06 Oct 2020 19:09:48
	System	06 Oct 2020 19:09:48

US3502142

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-06T13:09:31', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '9cd2fc6b-26ea-4f6a-b0b5-9d0177fedf4d'	System	06 Oct 2020 19:09:48
User entered 'No (N)'	System	06 Oct 2020 19:09:48

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-06T13:09:35', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '9cd2fc6b-26ea-4f6a-b0b5-9d0177fedf4d' User entered '06 Oct 2020 13:09'	System	06 Oct 2020 19:09:48
	System	06 Oct 2020 19:09:48

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '06 Oct 2020 13:09'	System	06 Oct 2020 18:51:12



**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '06 Oct 2020 15:39'	System	06 Oct 2020 18:51:12

US3502142

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	06 Oct 2020 18:51:12
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 18:51:12

US3502142

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:57:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-06T16:34:26', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'a51b2873-8e34-4f88-a7f4-154295e0ed0d' User entered 'Yes (Y)'	System	06 Oct 2020 22:34:42
	System	06 Oct 2020 22:34:42

US3502142

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:57:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-06T16:34:31', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'a51b2873-8e34-4f88-a7f4-154295e0ed0d' User entered '97.1'	System	06 Oct 2020 22:34:42
	System	06 Oct 2020 22:34:42

US3502142

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-06T16:34:33', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'a51b2873-8e34-4f88-a7f4-154295e0ed0d' User entered 'No (N)'	System	06 Oct 2020 22:34:42
	System	06 Oct 2020 22:34:42

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-06T16:34:39', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'a51b2873-8e34-4f88-a7f4-154295e0ed0d' User entered '06 Oct 2020 16:34'	System	06 Oct 2020 22:34:42
	System	06 Oct 2020 22:34:42

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '06 Oct 2020 16:34'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 18:51:12



**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	06 Oct 2020 18:51:12
User entered 'Day 2'	System	06 Oct 2020 18:51:12

US3502142

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:57:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-07T20:40:07', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'a93ae81e-2cd9-41d9-b376-8a1b24348ba0' User entered 'Yes (Y)'	System	08 Oct 2020 02:40:25
	System	08 Oct 2020 02:40:25

US3502142

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:57:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-07T20:40:11', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'a93ae81e-2cd9-41d9-b376-8a1b24348ba0' User entered '97.1'	System	08 Oct 2020 02:40:25
	System	08 Oct 2020 02:40:25

US3502142

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-07T20:40:14', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'a93ae81e-2cd9-41d9-b376-8a1b24348ba0'	System	08 Oct 2020 02:40:25
User entered 'No (N)'	System	08 Oct 2020 02:40:25

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-07T20:40:20', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'a93ae81e-2cd9-41d9-b376-8a1b24348ba0' User entered '07 Oct 2020 20:40'	System	08 Oct 2020 02:40:25
	System	08 Oct 2020 02:40:25

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	06 Oct 2020 18:51:12
User entered 'Day 3'	System	06 Oct 2020 18:51:12



US3502142

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:57:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-08T18:40:39', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '9346e2d8-f703-462a-abeb-82311dd40b75' User entered 'Yes (Y)'	System	09 Oct 2020 00:40:53
	System	09 Oct 2020 00:40:53

US3502142

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:57:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-08T18:40:45', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '9346e2d8-f703-462a-abeb-82311dd40b75' User entered '98.1'	System	09 Oct 2020 00:40:53
	System	09 Oct 2020 00:40:53

US3502142

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-08T18:40:49', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '9346e2d8-f703-462a-abeb-82311dd40b75'	System	09 Oct 2020 00:40:53
User entered 'No (N)'	System	09 Oct 2020 00:40:53

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-08T18:40:52', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '9346e2d8-f703-462a-abeb-82311dd40b75' User entered '08 Oct 2020 18:40'	System	09 Oct 2020 00:40:53
	System	09 Oct 2020 00:40:53

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	06 Oct 2020 18:51:12
User entered 'Day 4'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 07:57:35**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-09T14:02:19', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'f5ac320a-39a3-42a9-9c81-cc1a6357dfe9' User entered 'Yes (Y)'	System	09 Oct 2020 20:02:48
	System	09 Oct 2020 20:02:48



US3502142

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:57:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-09T14:02:38', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'f5ac320a-39a3-42a9-9c81-cc1a6357dfe9' User entered '96.6'	System	09 Oct 2020 20:02:48
	System	09 Oct 2020 20:02:48

US3502142

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-09T14:02:41', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'f5ac320a-39a3-42a9-9c81-cc1a6357dfe9' User entered 'No (N)'	System	09 Oct 2020 20:02:48
	System	09 Oct 2020 20:02:48

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-09T14:02:44', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'f5ac320a-39a3-42a9-9c81-cc1a6357dfe9' User entered '09 Oct 2020 14:02'	System	09 Oct 2020 20:02:48
	System	09 Oct 2020 20:02:48

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	06 Oct 2020 18:51:12
User entered 'Day 5'	System	06 Oct 2020 18:51:12

US3502142

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:57:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06

US3502142

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:57:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06



US3502142

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06

US3502142

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06

US3502142

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:57:35

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	06 Oct 2020 18:51:12
User entered 'Day 6'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 07:57:35**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-11T12:00:23', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '3e149c20-7dbb-4ac2-a298-c1b7ac4f44b9' User entered 'Yes (Y)'	System	11 Oct 2020 18:00:37
	System	11 Oct 2020 18:00:37



US3502142

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:57:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-11T12:00:28', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '3e149c20-7dbb-4ac2-a298-c1b7ac4f44b9' User entered '96.9'	System	11 Oct 2020 18:00:37
	System	11 Oct 2020 18:00:37

US3502142

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-11T12:00:31', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '3e149c20-7dbb-4ac2-a298-c1b7ac4f44b9'	System	11 Oct 2020 18:00:37
User entered 'No (N)'	System	11 Oct 2020 18:00:37

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-11T12:00:34', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '3e149c20-7dbb-4ac2-a298-c1b7ac4f44b9' User entered '11 Oct 2020 12:00'	System	11 Oct 2020 18:00:37
	System	11 Oct 2020 18:00:37

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 18:51:12

US3502142

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	06 Oct 2020 18:51:12
User entered 'Day 7'	System	06 Oct 2020 18:51:12

US3502142

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:57:35

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-13T01:27:04', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '00656df6-34be-4e1b-adf9-fb9365565005' User entered 'Yes (Y)'	System	13 Oct 2020 07:27:22
	System	13 Oct 2020 07:27:22

US3502142

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:57:35

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-13T01:27:10', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '00656df6-34be-4e1b-adf9-fb9365565005' User entered '96.9'	System	13 Oct 2020 07:27:22
	System	13 Oct 2020 07:27:22



US3502142

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-13T01:27:14', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '00656df6-34be-4e1b-adf9-fb9365565005'	System	13 Oct 2020 07:27:22
User entered 'No (N)'	System	13 Oct 2020 07:27:22

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-13T01:27:19', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '00656df6-34be-4e1b-adf9-fb9365565005' User entered '13 Oct 2020 01:27'	System	13 Oct 2020 07:27:22
	System	13 Oct 2020 07:27:22

US3502142

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:57:35

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	06 Oct 2020 18:51:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 18:51:12

US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-06T13:09:48', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '68d2698b-a61e-4c8a-84ae-8694b65627f5' User entered 'None (1)'	System	06 Oct 2020 19:10:06
	System	06 Oct 2020 19:10:06

US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:57:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-06T13:09:51', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '68d2698b-a61e-4c8a-84ae-8694b65627f5' User entered 'No (N)'	System	06 Oct 2020 19:10:06
	System	06 Oct 2020 19:10:06

US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-06T13:09:54', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '68d2698b-a61e-4c8a-84ae-8694b65627f5' User entered 'No (N)'	System	06 Oct 2020 19:10:06
	System	06 Oct 2020 19:10:06



US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-06T13:09:57', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '68d2698b-a61e-4c8a-84ae-8694b65627f5' User entered 'None (1)'	System	06 Oct 2020 19:10:06
	System	06 Oct 2020 19:10:06

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-06T13:10:00', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '68d2698b-a61e-4c8a-84ae-8694b65627f5' User entered '06 Oct 2020 13:10'	System	06 Oct 2020 19:10:06
	System	06 Oct 2020 19:10:06

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '06 Oct 2020 13:09'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '06 Oct 2020 15:39'	System	06 Oct 2020 18:51:12

US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	06 Oct 2020 18:51:12
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 18:51:12

US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-06T16:34:43', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '545b2250-ccf5-4294-94da-ca98002dd455'	System	06 Oct 2020 22:34:56
User entered 'None (1)'	System	06 Oct 2020 22:34:56

US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-06T16:34:45', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '545b2250-ccf5-4294-94da-ca98002dd455'	System	06 Oct 2020 22:34:56
User entered 'No (N)'	System	06 Oct 2020 22:34:56

US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-06T16:34:48', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '545b2250-ccf5-4294-94da-ca98002dd455'	System	06 Oct 2020 22:34:56
User entered 'No (N)'	System	06 Oct 2020 22:34:56



US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-06T16:34:50', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '545b2250-ccf5-4294-94da-ca98002dd455'	System	06 Oct 2020 22:34:56
User entered 'None (1)'	System	06 Oct 2020 22:34:56

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-06T16:34:54', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '545b2250-ccf5-4294-94da-ca98002dd455' User entered '06 Oct 2020 16:34'	System	06 Oct 2020 22:34:56
	System	06 Oct 2020 22:34:56

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '06 Oct 2020 16:34'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 18:51:12

US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:57:35

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	06 Oct 2020 18:51:12
User entered 'Day 2'	System	06 Oct 2020 18:51:12

US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-07T20:40:24', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '6f82b188-ae33-4e4c-9491-7ea742b92883'	System	08 Oct 2020 02:40:37
User entered 'None (1)'	System	08 Oct 2020 02:40:37

US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:57:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-07T20:40:27', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '6f82b188-ae33-4e4c-9491-7ea742b92883' User entered 'No (N)'	System	08 Oct 2020 02:40:37
	System	08 Oct 2020 02:40:37

US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-07T20:40:30', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '6f82b188-ae33-4e4c-9491-7ea742b92883' User entered 'No (N)'	System	08 Oct 2020 02:40:37
	System	08 Oct 2020 02:40:37



US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-07T20:40:32', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '6f82b188-ae33-4e4c-9491-7ea742b92883'	System	08 Oct 2020 02:40:37
User entered 'None (1)'	System	08 Oct 2020 02:40:37

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-07T20:40:35', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '6f82b188-ae33-4e4c-9491-7ea742b92883' User entered '07 Oct 2020 20:40'	System	08 Oct 2020 02:40:37
	System	08 Oct 2020 02:40:37

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	06 Oct 2020 18:51:12
User entered 'Day 3'	System	06 Oct 2020 18:51:12

US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-08T18:40:57', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '000ec02a-3bda-4a25-9029-441e8be680ab' User entered 'None (1)'	System	09 Oct 2020 00:41:12
	System	09 Oct 2020 00:41:12

US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:57:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-08T18:41:00', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '000ec02a-3bda-4a25-9029-441e8be680ab' User entered 'No (N)'	System	09 Oct 2020 00:41:12
	System	09 Oct 2020 00:41:12

US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-08T18:41:02', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '000ec02a-3bda-4a25-9029-441e8be680ab' User entered 'No (N)'	System	09 Oct 2020 00:41:12
	System	09 Oct 2020 00:41:12



US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-08T18:41:06', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '000ec02a-3bda-4a25-9029-441e8be680ab' User entered 'None (1)'	System	09 Oct 2020 00:41:12
	System	09 Oct 2020 00:41:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-08T18:41:09', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '000ec02a-3bda-4a25-9029-441e8be680ab' User entered '08 Oct 2020 18:41'	System	09 Oct 2020 00:41:12
	System	09 Oct 2020 00:41:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	06 Oct 2020 18:51:12
User entered 'Day 4'	System	06 Oct 2020 18:51:12

US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-09T14:02:49', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '27b7161f-21f9-4fa7-a790-4209ae4e1fe9' User entered 'None (1)'	System	09 Oct 2020 20:03:04
	System	09 Oct 2020 20:03:04

US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:57:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-09T14:02:51', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '27b7161f-21f9-4fa7-a790-4209ae4e1fe9' User entered 'No (N)'	System	09 Oct 2020 20:03:04
	System	09 Oct 2020 20:03:04

US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-09T14:02:55', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '27b7161f-21f9-4fa7-a790-4209ae4e1fe9' User entered 'No (N)'	System	09 Oct 2020 20:03:04
	System	09 Oct 2020 20:03:04



US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-09T14:02:57', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '27b7161f-21f9-4fa7-a790-4209ae4e1fe9'	System	09 Oct 2020 20:03:04
User entered 'None (1)'	System	09 Oct 2020 20:03:04

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-09T14:03:01', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '27b7161f-21f9-4fa7-a790-4209ae4e1fe9' User entered '09 Oct 2020 14:03'	System	09 Oct 2020 20:03:04
	System	09 Oct 2020 20:03:04

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	06 Oct 2020 18:51:12
User entered 'Day 5'	System	06 Oct 2020 18:51:12

US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06

US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:57:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06

US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06



US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06

US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06

US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	06 Oct 2020 18:51:12
User entered 'Day 6'	System	06 Oct 2020 18:51:12

US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-11T12:00:38', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'a7de5a53-6b02-4baa-a83b-715f4a8ea0d0'	System	11 Oct 2020 18:00:51
User entered 'None (1)'	System	11 Oct 2020 18:00:51



US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:57:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-11T12:00:40', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'a7de5a53-6b02-4baa-a83b-715f4a8ea0d0'	System	11 Oct 2020 18:00:51
User entered 'No (N)'	System	11 Oct 2020 18:00:51

US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-11T12:00:43', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'a7de5a53-6b02-4baa-a83b-715f4a8ea0d0' User entered 'No (N)'	System	11 Oct 2020 18:00:51
	System	11 Oct 2020 18:00:51

US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-11T12:00:46', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'a7de5a53-6b02-4baa-a83b-715f4a8ea0d0'	System	11 Oct 2020 18:00:51
User entered 'None (1)'	System	11 Oct 2020 18:00:51

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-11T12:00:49', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'a7de5a53-6b02-4baa-a83b-715f4a8ea0d0' User entered '11 Oct 2020 12:00'	System	11 Oct 2020 18:00:51
	System	11 Oct 2020 18:00:51

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	06 Oct 2020 18:51:12
User entered 'Day 7'	System	06 Oct 2020 18:51:12

US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-13T01:27:23', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'da8c1ca2-e79a-4bec-97ac-4d2880db4614' User entered 'None (1)'	System	13 Oct 2020 07:27:34
	System	13 Oct 2020 07:27:34



US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:57:35

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-13T01:27:25', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'da8c1ca2-e79a-4bec-97ac-4d2880db4614' User entered 'No (N)'	System	13 Oct 2020 07:27:34
	System	13 Oct 2020 07:27:34

US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:57:35

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-13T01:27:27', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'da8c1ca2-e79a-4bec-97ac-4d2880db4614' User entered 'No (N)'	System	13 Oct 2020 07:27:34
	System	13 Oct 2020 07:27:34

US3502142

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-13T01:27:29', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'da8c1ca2-e79a-4bec-97ac-4d2880db4614' User entered 'None (1)'	System	13 Oct 2020 07:27:34
	System	13 Oct 2020 07:27:34

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-13T01:27:33', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'da8c1ca2-e79a-4bec-97ac-4d2880db4614' User entered '13 Oct 2020 01:27'	System	13 Oct 2020 07:27:34
	System	13 Oct 2020 07:27:34

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	06 Oct 2020 18:51:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:57:35**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-06T13:10:11', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '5e8df29f-5904-400f-910a-6fb592069c04' User entered 'None (0)'	System	06 Oct 2020 19:10:26
	System	06 Oct 2020 19:10:26



**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:57:35**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-06T13:10:13', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '5e8df29f-5904-400f-910a-6fb592069c04' User entered 'None (0)'	System	06 Oct 2020 19:10:26
	System	06 Oct 2020 19:10:26

US3502142

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:57:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-06T13:10:14', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '5e8df29f-5904-400f-910a-6fb592069c04' User entered 'None (0)'	System	06 Oct 2020 19:10:26
	System	06 Oct 2020 19:10:26

US3502142

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:57:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-06T13:10:16', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '5e8df29f-5904-400f-910a-6fb592069c04' User entered 'None (0)'	System	06 Oct 2020 19:10:26
	System	06 Oct 2020 19:10:26

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:57:35**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-06T13:10:17', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '5e8df29f-5904-400f-910a-6fb592069c04' User entered 'None (0)'	System	06 Oct 2020 19:10:26
	System	06 Oct 2020 19:10:26

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:57:35**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-06T13:10:19', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '5e8df29f-5904-400f-910a-6fb592069c04' User entered 'None (0)'	System	06 Oct 2020 19:10:26
	System	06 Oct 2020 19:10:26

US3502142

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-06T13:10:20', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '5e8df29f-5904-400f-910a-6fb592069c04' User entered 'No (N)'	System	06 Oct 2020 19:10:26
	System	06 Oct 2020 19:10:26

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-06T13:10:24', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '5e8df29f-5904-400f-910a-6fb592069c04' User entered '06 Oct 2020 13:10'	System	06 Oct 2020 19:10:26
	System	06 Oct 2020 19:10:26

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '06 Oct 2020 13:09'	System	06 Oct 2020 18:51:12



**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '06 Oct 2020 15:39'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	06 Oct 2020 18:51:12
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:57:35**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-06T16:34:58', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'edc8824e-f46d-472d-a0a2-50526ab7a6f6' User entered 'None (0)'	System	06 Oct 2020 22:35:18
	System	06 Oct 2020 22:35:18

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:57:35**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-06T16:35:01', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'edc8824e-f46d-472d-a0a2-50526ab7a6f6' User entered 'None (0)'	System	06 Oct 2020 22:35:18
	System	06 Oct 2020 22:35:18

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:57:35**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-06T16:35:02', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'edc8824e-f46d-472d-a0a2-50526ab7a6f6' User entered 'None (0)'	System	06 Oct 2020 22:35:18
	System	06 Oct 2020 22:35:18

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:57:35**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-06T16:35:04', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'edc8824e-f46d-472d-a0a2-50526ab7a6f6' User entered 'None (0)'	System	06 Oct 2020 22:35:18
	System	06 Oct 2020 22:35:18

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:57:35**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-06T16:35:07', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'edc8824e-f46d-472d-a0a2-50526ab7a6f6' User entered 'None (0)'	System	06 Oct 2020 22:35:18
	System	06 Oct 2020 22:35:18

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:57:35**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-06T16:35:09', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'edc8824e-f46d-472d-a0a2-50526ab7a6f6' User entered 'None (0)'	System	06 Oct 2020 22:35:18
	System	06 Oct 2020 22:35:18



US3502142

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-06T16:35:12', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'edc8824e-f46d-472d-a0a2-50526ab7a6f6' User entered 'No (N)'	System	06 Oct 2020 22:35:18
	System	06 Oct 2020 22:35:18

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-06T16:35:16', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'edc8824e-f46d-472d-a0a2-50526ab7a6f6' User entered '06 Oct 2020 16:35'	System	06 Oct 2020 22:35:18
	System	06 Oct 2020 22:35:18

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '06 Oct 2020 16:34'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	06 Oct 2020 18:51:12
User entered 'Day 2'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:57:35**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-07T20:40:39', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '42d26b85-0697-4a60-bacc-7cf0abe1baa6' User entered 'None (0)'	System	08 Oct 2020 02:40:59
	System	08 Oct 2020 02:40:59

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:57:35**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-07T20:40:41', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '42d26b85-0697-4a60-bacc-7cf0abe1baa6' User entered 'None (0)'	System	08 Oct 2020 02:40:59
	System	08 Oct 2020 02:40:59

US3502142

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:57:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-07T20:40:43', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '42d26b85-0697-4a60-bacc-7cf0abe1baa6' User entered 'None (0)'	System	08 Oct 2020 02:40:59
	System	08 Oct 2020 02:40:59



US3502142

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:57:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-07T20:40:47', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '42d26b85-0697-4a60-bacc-7cf0abe1baa6' User entered 'None (0)'	System	08 Oct 2020 02:40:59
	System	08 Oct 2020 02:40:59

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:57:35**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-07T20:40:49', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '42d26b85-0697-4a60-bacc-7cf0abe1baa6' User entered 'None (0)'	System	08 Oct 2020 02:40:59
	System	08 Oct 2020 02:40:59

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:57:35**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-07T20:40:51', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '42d26b85-0697-4a60-bacc-7cf0abe1baa6' User entered 'None (0)'	System	08 Oct 2020 02:40:59
	System	08 Oct 2020 02:40:59

US3502142

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-07T20:40:54', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '42d26b85-0697-4a60-bacc-7cf0abe1baa6' User entered 'No (N)'	System	08 Oct 2020 02:40:59
	System	08 Oct 2020 02:40:59

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-07T20:40:57', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '42d26b85-0697-4a60-bacc-7cf0abe1baa6' User entered '07 Oct 2020 20:40'	System	08 Oct 2020 02:40:59
	System	08 Oct 2020 02:40:59

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	06 Oct 2020 18:51:12
User entered 'Day 3'	System	06 Oct 2020 18:51:12



**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:57:35**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-08T18:41:14', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'b5f7a065-3dee-4242-b0a2-659903339bc7' User entered 'None (0)'	System	09 Oct 2020 00:41:41
	System	09 Oct 2020 00:41:41

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:57:35**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-08T18:41:18', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'b5f7a065-3dee-4242-b0a2-659903339bc7' User entered 'None (0)'	System	09 Oct 2020 00:41:41
	System	09 Oct 2020 00:41:41

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:57:35**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-08T18:41:21', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'b5f7a065-3dee-4242-b0a2-659903339bc7' User entered 'None (0)'	System	09 Oct 2020 00:41:41
	System	09 Oct 2020 00:41:41

US3502142

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:57:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-08T18:41:23', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'b5f7a065-3dee-4242-b0a2-659903339bc7' User entered 'None (0)'	System	09 Oct 2020 00:41:41
	System	09 Oct 2020 00:41:41

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:57:35**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-08T18:41:28', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'b5f7a065-3dee-4242-b0a2-659903339bc7' User entered 'None (0)'	System	09 Oct 2020 00:41:41
	System	09 Oct 2020 00:41:41

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:57:35**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-08T18:41:30', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'b5f7a065-3dee-4242-b0a2-659903339bc7' User entered 'None (0)'	System	09 Oct 2020 00:41:41
	System	09 Oct 2020 00:41:41

US3502142

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-08T18:41:34', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'b5f7a065-3dee-4242-b0a2-659903339bc7'	System	09 Oct 2020 00:41:41
User entered 'No (N)'	System	09 Oct 2020 00:41:41

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-08T18:41:38', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'b5f7a065-3dee-4242-b0a2-659903339bc7' User entered '08 Oct 2020 18:41'	System	09 Oct 2020 00:41:41
	System	09 Oct 2020 00:41:41



**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	06 Oct 2020 18:51:12
User entered 'Day 4'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:57:35**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-09T14:03:13', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '9886556b-02a8-4ec1-913c-faf40040e98c' User entered 'None (0)'	System	09 Oct 2020 20:03:39
	System	09 Oct 2020 20:03:39

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:57:35**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-09T14:03:17', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '9886556b-02a8-4ec1-913c-faf40040e98c' User entered 'None (0)'	System	09 Oct 2020 20:03:39
	System	09 Oct 2020 20:03:39

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:57:35**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-09T14:03:18', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '9886556b-02a8-4ec1-913c-faf40040e98c' User entered 'None (0)'	System	09 Oct 2020 20:03:39
	System	09 Oct 2020 20:03:39

US3502142

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:57:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-09T14:03:20', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '9886556b-02a8-4ec1-913c-faf40040e98c' User entered 'None (0)'	System	09 Oct 2020 20:03:39
	System	09 Oct 2020 20:03:39

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:57:35**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-09T14:03:22', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '9886556b-02a8-4ec1-913c-faf40040e98c' User entered 'None (0)'	System	09 Oct 2020 20:03:39
	System	09 Oct 2020 20:03:39



**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:57:35**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-09T14:03:24', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '9886556b-02a8-4ec1-913c-faf40040e98c' User entered 'None (0)'	System	09 Oct 2020 20:03:39
	System	09 Oct 2020 20:03:39

US3502142

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-09T14:03:27', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '9886556b-02a8-4ec1-913c-faf40040e98c' User entered 'No (N)'	System	09 Oct 2020 20:03:39
	System	09 Oct 2020 20:03:39

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-09T14:03:30', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '9886556b-02a8-4ec1-913c-faf40040e98c' User entered '09 Oct 2020 14:03'	System	09 Oct 2020 20:03:39
	System	09 Oct 2020 20:03:39

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	06 Oct 2020 18:51:12
User entered 'Day 5'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:57:35**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:57:35**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06



US3502142

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:57:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06

US3502142

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:57:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:57:35**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:57:35**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06

US3502142

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 18:51:12



**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	06 Oct 2020 18:51:12
User entered 'Day 6'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:57:35**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-11T12:00:53', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'a4f8c944-9140-4306-b69b-35db1cbdbdb4' User entered 'None (0)'	System	11 Oct 2020 18:01:17
	System	11 Oct 2020 18:01:17

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:57:35**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-11T12:00:55', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'a4f8c944-9140-4306-b69b-35db1cbdbdb4' User entered 'None (0)'	System	11 Oct 2020 18:01:17
	System	11 Oct 2020 18:01:17

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:57:35**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-11T12:00:57', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'a4f8c944-9140-4306-b69b-35db1cbdbdb4' User entered 'None (0)'	System	11 Oct 2020 18:01:17
	System	11 Oct 2020 18:01:17

US3502142

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:57:35

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-11T12:00:59', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'a4f8c944-9140-4306-b69b-35db1cbdbdb4' User entered 'None (0)'	System	11 Oct 2020 18:01:17
	System	11 Oct 2020 18:01:17

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:57:35**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-11T12:01:02', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'a4f8c944-9140-4306-b69b-35db1cbdbdb4' User entered 'None (0)'	System	11 Oct 2020 18:01:17
	System	11 Oct 2020 18:01:17

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:57:35**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-11T12:01:04', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'a4f8c944-9140-4306-b69b-35db1cbdbdb4' User entered 'None (0)'	System	11 Oct 2020 18:01:17
	System	11 Oct 2020 18:01:17

US3502142

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-11T12:01:07', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'a4f8c944-9140-4306-b69b-35db1cbdbdb4' User entered 'No (N)'	System	11 Oct 2020 18:01:17
	System	11 Oct 2020 18:01:17



**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-11T12:01:10', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'a4f8c944-9140-4306-b69b-35db1cbdbdb4' User entered '11 Oct 2020 12:01'	System	11 Oct 2020 18:01:17
	System	11 Oct 2020 18:01:17

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
Data entry locked.	System	06 Oct 2020 18:51:12
User entered 'Day 7'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:57:35**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-13T01:27:37', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '0b49c2ef-5814-4ae6-a003-43bb5c111b02' User entered 'None (0)'	System	13 Oct 2020 07:27:56
	System	13 Oct 2020 07:27:56

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:57:35**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-13T01:27:40', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '0b49c2ef-5814-4ae6-a003-43bb5c111b02' User entered 'None (0)'	System	13 Oct 2020 07:27:56
	System	13 Oct 2020 07:27:56

US3502142

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:57:35

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-13T01:27:43', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '0b49c2ef-5814-4ae6-a003-43bb5c111b02' User entered 'None (0)'	System	13 Oct 2020 07:27:56
	System	13 Oct 2020 07:27:56

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:57:35**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-13T01:27:45', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '0b49c2ef-5814-4ae6-a003-43bb5c111b02' User entered 'None (0)'	System	13 Oct 2020 07:27:56
	System	13 Oct 2020 07:27:56



**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:57:35**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-13T01:27:46', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '0b49c2ef-5814-4ae6-a003-43bb5c111b02' User entered 'None (0)'	System	13 Oct 2020 07:27:56
	System	13 Oct 2020 07:27:56

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:57:35**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-13T01:27:48', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '0b49c2ef-5814-4ae6-a003-43bb5c111b02' User entered 'None (0)'	System	13 Oct 2020 07:27:56
	System	13 Oct 2020 07:27:56

US3502142

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:57:35

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 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-13T01:27:51', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '0b49c2ef-5814-4ae6-a003-43bb5c111b02' User entered 'No (N)'	System	13 Oct 2020 07:27:56
	System	13 Oct 2020 07:27:56

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-10-13T01:27:54', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '0b49c2ef-5814-4ae6-a003-43bb5c111b02'	System	13 Oct 2020 07:27:56
User entered '13 Oct 2020 01:27'	System	13 Oct 2020 07:27:56

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:57:35**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:44:06
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 18:51:12

**US3502142**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	Patrishia Adkins (b) (4)	19 Oct 2020 19:06:55

**US3502142**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '13 Oct 2020'	Patrishia Adkins (b) (4)	19 Oct 2020 19:06:55



**US3502142**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Contact Not Made (CONTACT NOT MADE)'	Patrishia Adkins (b) (4)	19 Oct 2020 19:06:55

**US3502142**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Attempted X3'	Patrishia Adkins (b) (4)	19 Oct 2020 19:06:55

**US3502142**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:35**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	Patrishia Adkins (b) (4)	19 Oct 2020 19:07:02

**US3502142**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'I'	System	19 Oct 2020 19:07:02

**US3502142**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	Patrishia Adkins (b) (4)	22 Oct 2020 22:24:20

**US3502142**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '20 Oct 2020'	Patrishia Adkins (b) (4)	22 Oct 2020 22:24:20

**US3502142**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Contact Made (CONTACT MADE)'	Patrishia Adkins (b) (4)	22 Oct 2020 22:24:20

**US3502142**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	Patrishia Adkins (b) (4)	22 Oct 2020 22:24:20



**US3502142**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:35**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	Patrishia Adkins (b) (4)	22 Oct 2020 22:24:25

**US3502142**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'I'	System	22 Oct 2020 22:24:25

**US3502142**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	Patrishia Adkins (b) (4)	28 Oct 2020 15:57:43

**US3502142**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '27 Oct 2020'	Patrishia Adkins (b) (4)	28 Oct 2020 15:57:43

**US3502142**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Contact Made (CONTACT MADE)'	Patrishia Adkins (b) (4)	28 Oct 2020 15:57:43

US3502142

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:35

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	Patrishia Adkins (b) (4)	28 Oct 2020 15:57:43

**US3502142**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:35**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	Patrishia Adkins (b) (4)	28 Oct 2020 15:57:50

**US3502142**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'I'	System	28 Oct 2020 15:57:50



**US3502142**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:57:35**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:09:08

**US3502142**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '3 Nov 2020'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:09:08

**US3502142**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:09:08

**US3502142**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:57:35**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'VISIT3'	System	03 Nov 2020 21:09:08

**US3502142**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:09:34

US3502142

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:35

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User closed query 'Per CDM: Per CCG, Date should be recorded in (dd MMM yyyy) format. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 07:48:38
Query 'Per CDM: Per CCG, Date should be recorded in (dd MMM yyyy) format. Please review and update accordingly. ' answered with 'Done' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 01:53:36
User entered '03 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 01:53:32
User opened query 'Per CDM: Per CCG, Date should be recorded in (dd MMM yyyy) format. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 12:11:49
User entered '3 Nov 2020'	(b) (4), (b) (6)	03 Nov 2020 21:09:34

**US3502142**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '12:29'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:09:34

**US3502142**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered '03 Nov 2020 12:29'	System	12 Nov 2020 01:53:32
User entered '3 Nov 2020 12:29'	System	03 Nov 2020 21:09:34



US3502142

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '97.1' F	(b) (4), (b) (6)	03 Nov 2020 21:09:34

**US3502142**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:09:34

**US3502142**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Forehead'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:09:34

**US3502142**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '79'	(b) (4), (b) (6)	03 Nov 2020 21:09:34

**US3502142**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'bpm'	System	03 Nov 2020 21:09:34

**US3502142**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '14'	(b) (4), (b) (6)	03 Nov 2020 21:09:34

**US3502142**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'breaths/min'	System	03 Nov 2020 21:09:34

**US3502142**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '116'	(b) (4), (b) (6)	03 Nov 2020 21:09:34



**US3502142**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'mmHg'	System	03 Nov 2020 21:09:34

**US3502142**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '69'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:09:34

**US3502142**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'mmHg'	System	03 Nov 2020 21:09:34

**US3502142**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00

**US3502142**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00

**US3502142**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:57:35**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 22:19:22
User entered 'Yes (Y)'		03 Nov 2020 21:10:20

**US3502142**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:57:35**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 22:19:22
User entered '3 Nov 2020'		03 Nov 2020 21:10:20

**US3502142**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:57:35**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 21:10:30



**US3502142**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:57:35**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '3 Nov 2020'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:10:30

**US3502142**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:57:35**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '13:00'	(b) (4) (b) (4), (b) (6)	03 Nov 2020 21:10:30

**US3502142**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:57:35**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered '3 Nov 2020 13:00'	System	03 Nov 2020 21:10:30

**US3502142**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:35**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 21:08:56

**US3502142**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'I'	System	03 Nov 2020 21:08:56

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27
Data entry locked.	System	11 Sep 2020 15:11:36
User entered 'Day 64'	System	11 Sep 2020 15:11:36

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27



**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27



**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27



**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27
Data entry locked.	System	11 Sep 2020 15:11:36
User entered '11 Nov 2020 00:01'	System	11 Sep 2020 15:11:36



**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27
Data entry locked.	System	11 Sep 2020 15:11:36
User entered '15 Nov 2020 23:59'	System	11 Sep 2020 15:11:36

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27
Data entry locked.	System	11 Sep 2020 15:11:36
User entered 'Day 71'	System	11 Sep 2020 15:11:36

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27



**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27



**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27



**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27
Data entry locked.	System	11 Sep 2020 15:11:36
User entered '18 Nov 2020 00:01'	System	11 Sep 2020 15:11:36

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 07:34:27
Data entry locked.	System	11 Sep 2020 15:11:36
User entered '22 Nov 2020 23:59'	System	11 Sep 2020 15:11:36

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-11-24T13:25:28', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '06dd1dde-cd15-4985-8a6f-4a22d6fc10f7'	System	24 Nov 2020 20:25:41
User entered 'No (N)'	System	24 Nov 2020 20:25:41

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

Have you been exposed to someone with 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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-11-24T13:25:32', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '06dd1dde-cd15-4985-8a6f-4a22d6fc10f7'	System	24 Nov 2020 20:25:41
User entered 'No (N)'	System	24 Nov 2020 20:25:41



**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-11-24T13:25:36', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '06dd1dde-cd15-4985-8a6f-4a22d6fc10f7'	System	24 Nov 2020 20:25:41
User entered '24 Nov 2020 13:25:36'	System	24 Nov 2020 20:25:41

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-12-01T12:15:15', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '3a9fce18-54e5-4a64-aafb-e4f6036c730d' User entered 'No (N)'	System	01 Dec 2020 19:15:26
	System	01 Dec 2020 19:15:26

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

Have you been exposed to someone with 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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-12-01T12:15:18', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '3a9fce18-54e5-4a64-aafb-e4f6036c730d' User entered 'No (N)'	System	01 Dec 2020 19:15:26

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-12-01T12:15:24', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '3a9fce18-54e5-4a64-aafb-e4f6036c730d' User entered '01 Dec 2020 12:15:24'	System	01 Dec 2020 19:15:26
	System	01 Dec 2020 19:15:26

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 07:34:27



**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-12-09T19:37:20', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'c1b48244-28b0-4077-a2e4-426fbe7b8767' User entered 'No (N)'	System	10 Dec 2020 02:37:32
	System	10 Dec 2020 02:37:32

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

Have you been exposed to someone with 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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-12-09T19:37:23', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'c1b48244-28b0-4077-a2e4-426fbe7b8767' User entered 'No (N)'	System	10 Dec 2020 02:37:32
	System	10 Dec 2020 02:37:32

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-12-09T19:37:28', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'c1b48244-28b0-4077-a2e4-426fbe7b8767' User entered '09 Dec 2020 19:37:28'	System	10 Dec 2020 02:37:32
	System	10 Dec 2020 02:37:32

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 07:34:27



**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-12-13T16:30:14', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '4842c0b7-744a-4158-b5d5-60222aea4bfc' User entered 'No (N)'	System	13 Dec 2020 23:30:24
	System	13 Dec 2020 23:30:24

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

Have you been exposed to someone with 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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-12-13T16:30:16', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '4842c0b7-744a-4158-b5d5-60222aea4bfc' User entered 'No (N)'	System	13 Dec 2020 23:30:24
	System	13 Dec 2020 23:30:24

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-12-13T16:30:22', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '4842c0b7-744a-4158-b5d5-60222aea4bfc' User entered '13 Dec 2020 16:30:22'	System	13 Dec 2020 23:30:24
	System	13 Dec 2020 23:30:24

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-12-24T11:59:32', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '5f894dc4-6a42-4899-9947-3ebee053da3' User entered 'No (N)'	System	24 Dec 2020 18:59:48
	System	24 Dec 2020 18:59:48

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

Have you been exposed to someone with 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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-12-24T11:59:36', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '5f894dc4-6a42-4899-9947-3ebee053da3' User entered 'No (N)'	System	24 Dec 2020 18:59:48
	System	24 Dec 2020 18:59:48



**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-12-24T11:59:44', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '5f894dc4-6a42-4899-9947-3ebee053da3' User entered '24 Dec 2020 11:59:44'	System	24 Dec 2020 18:59:48
	System	24 Dec 2020 18:59:48

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-12-29T12:00:17', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '1daabf18-f687-47c4-afc1-419b7fe7988a' User entered 'No (N)'	System	29 Dec 2020 19:00:53
	System	29 Dec 2020 19:00:53

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

Have you been exposed to someone with 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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-12-29T12:00:23', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '1daabf18-f687-47c4-afc1-419b7fe7988a' User entered 'No (N)'	System	29 Dec 2020 19:00:53

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2020-12-29T12:00:30', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '1daabf18-f687-47c4-afc1-419b7fe7988a' User entered '29 Dec 2020 12:00:30'	System	29 Dec 2020 19:00:53
	System	29 Dec 2020 19:00:53

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 07:34:27



**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-01-05T21:13:52', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'c3b80a7e-a425-4d4a-a5e9-d4abe4732338' User entered 'No (N)'	System	06 Jan 2021 04:14:04
	System	06 Jan 2021 04:14:04

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

Have you been exposed to someone with 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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-01-05T21:13:56', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'c3b80a7e-a425-4d4a-a5e9-d4abe4732338'	System	06 Jan 2021 04:14:04
User entered 'No (N)'	System	06 Jan 2021 04:14:04

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-01-05T21:14:02', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'c3b80a7e-a425-4d4a-a5e9-d4abe4732338' User entered '05 Jan 2021 21:14:02'	System	06 Jan 2021 04:14:04
	System	06 Jan 2021 04:14:04

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 07:34:27



**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-01-12T12:00:21', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'a760aac5-e0a1-48a7-9216-dccf290593dd'	System	12 Jan 2021 19:00:58
User entered 'No (N)'	System	12 Jan 2021 19:00:58

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

Have you been exposed to someone with 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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-01-12T12:00:24', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'a760aac5-e0a1-48a7-9216-dccf290593dd' User entered 'No (N)'	System	12 Jan 2021 19:00:58

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-01-12T12:00:28', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'a760aac5-e0a1-48a7-9216-dccf290593dd' User entered '12 Jan 2021 12:00:28'	System	12 Jan 2021 19:00:58
	System	12 Jan 2021 19:00:58

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-01-19T12:01:03', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'ae921716-c9be-414b-b3e6-f8fdc39325cd' User entered 'No (N)'	System	19 Jan 2021 19:01:31

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

Have you been exposed to someone with 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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-01-19T12:01:20', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'ae921716-c9be-414b-b3e6-f8fdc39325cd' User entered 'No (N)'	System	19 Jan 2021 19:01:31



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-01-19T12:01:28', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'ae921716-c9be-414b-b3e6-f8fdc39325cd' User entered '19 Jan 2021 12:01:28'	System	19 Jan 2021 19:01:31

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-01-26T12:00:55', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '57ea5db5-ff60-4f92-b968-2417a6127cc6' User entered 'No (N)'	System	26 Jan 2021 20:05:35
	System	26 Jan 2021 20:05:35

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Have you been exposed to someone with 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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-01-26T12:00:58', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '57ea5db5-ff60-4f92-b968-2417a6127cc6'	System	26 Jan 2021 20:05:35
User entered 'No (N)'	System	26 Jan 2021 20:05:35

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-01-26T12:01:07', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '57ea5db5-ff60-4f92-b968-2417a6127cc6' User entered '26 Jan 2021 12:01:07'	System	26 Jan 2021 20:05:35
	System	26 Jan 2021 20:05:35

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 07:34:27



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-02-02T17:31:35', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '23ce6ed2-3885-445d-a9ef-aaa347408b21' User entered 'No (N)'	System	03 Feb 2021 00:31:45
	System	03 Feb 2021 00:31:45

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

Have you been exposed to someone with 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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-02-02T17:31:38', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '23ce6ed2-3885-445d-a9ef-aaa347408b21' User entered 'No (N)'	System	03 Feb 2021 00:31:45
	System	03 Feb 2021 00:31:45

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-02-02T17:31:43', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '23ce6ed2-3885-445d-a9ef-aaa347408b21' User entered '02 Feb 2021 17:31:43'	System	03 Feb 2021 00:31:45
	System	03 Feb 2021 00:31:45

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 07:34:27



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-02-09T12:00:37', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '132ea18c-9997-431b-9b10-8ac74adf6d1e' User entered 'No (N)'	System	09 Feb 2021 19:02:02
	System	09 Feb 2021 19:02:02

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Have you been exposed to someone with 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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-02-09T12:00:39', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '132ea18c-9997-431b-9b10-8ac74adf6d1e' User entered 'No (N)'	System	09 Feb 2021 19:02:02
	System	09 Feb 2021 19:02:02

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-02-09T12:01:34', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '132ea18c-9997-431b-9b10-8ac74adf6d1e' User entered '09 Feb 2021 12:01:34'	System	09 Feb 2021 19:02:02
	System	09 Feb 2021 19:02:02

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-02-16T12:00:43', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '6a86b13e-1fd3-4237-aec3-4114c08a0df9' User entered 'No (N)'	System	16 Feb 2021 19:00:52
	System	16 Feb 2021 19:00:52

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

Have you been exposed to someone with 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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-02-16T12:00:45', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '6a86b13e-1fd3-4237-aec3-4114c08a0df9' User entered 'No (N)'	System	16 Feb 2021 19:00:52
	System	16 Feb 2021 19:00:52



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-02-16T12:00:49', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '6a86b13e-1fd3-4237-aec3-4114c08a0df9' User entered '16 Feb 2021 12:00:49'	System	16 Feb 2021 19:00:52
	System	16 Feb 2021 19:00:52

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-03-02T20:40:22-07:00', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '9bb5bcc2-7acf-40be-8343-8fd68584b9f3'	System	03 Mar 2021 03:40:39
User entered 'No (N)'	System	03 Mar 2021 03:40:39



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

Have you been exposed to someone with 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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-03-02T20:40:25-07:00', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '9bb5bcc2-7acf-40be-8343-8fd68584b9f3'	System	03 Mar 2021 03:40:39
User entered 'No (N)'	System	03 Mar 2021 03:40:39

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-03-02T20:40:30-07:00', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '9bb5bcc2-7acf-40be-8343-8fd68584b9f3'	System	03 Mar 2021 03:40:39
User entered '02 Mar 2021 20:40:30'	System	03 Mar 2021 03:40:39

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-03-09T12:00:19-07:00', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'f3bf1c79-8374-4c71-80f3-450879c77ab1'	System	09 Mar 2021 19:00:28
User entered 'No (N)'	System	09 Mar 2021 19:00:28

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

Have you been exposed to someone with 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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-03-09T12:00:21-07:00', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'f3bf1c79-8374-4c71-80f3-450879c77ab1'	System	09 Mar 2021 19:00:28
User entered 'No (N)'	System	09 Mar 2021 19:00:28

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-03-09T12:00:24-07:00', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'f3bf1c79-8374-4c71-80f3-450879c77ab1' User entered '09 Mar 2021 12:00:24'	System	09 Mar 2021 19:00:28
	System	09 Mar 2021 19:00:28



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-03-17T18:14:43-06:00', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '20c18405-5dc7-491e-b9a8-09da4972ac2e'	System	18 Mar 2021 00:14:50
User entered 'No (N)'	System	18 Mar 2021 00:14:50

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

Have you been exposed to someone with 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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-03-17T18:14:45-06:00', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '20c18405-5dc7-491e-b9a8-09da4972ac2e'	System	18 Mar 2021 00:14:50
User entered 'No (N)'	System	18 Mar 2021 00:14:50

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-03-17T18:14:48-06:00', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '20c18405-5dc7-491e-b9a8-09da4972ac2e'	System	18 Mar 2021 00:14:50
User entered '17 Mar 2021 18:14:48'	System	18 Mar 2021 00:14:50

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 07:34:27



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-03-23T12:00:20-06:00', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'daf5f3f3-b18c-4a99-a563-9dd8d84237f0'	System	23 Mar 2021 18:00:29
User entered 'No (N)'	System	23 Mar 2021 18:00:29

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

Have you been exposed to someone with 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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-03-23T12:00:22-06:00', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'daf5f3f3-b18c-4a99-a563-9dd8d84237f0'	System	23 Mar 2021 18:00:29
User entered 'No (N)'	System	23 Mar 2021 18:00:29

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-03-23T12:00:26-06:00', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'daf5f3f3-b18c-4a99-a563-9dd8d84237f0'	System	23 Mar 2021 18:00:29
User entered '23 Mar 2021 12:00:26'	System	23 Mar 2021 18:00:29

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-04-01T11:59:20-06:00', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'a13fa576-1f89-4509-920f-8bef1a927b3d' User entered 'No (N)'	System	01 Apr 2021 17:59:30
	System	01 Apr 2021 17:59:30



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

Have you been exposed to someone with 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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-04-01T11:59:23-06:00', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'a13fa576-1f89-4509-920f-8bef1a927b3d'	System	01 Apr 2021 17:59:30
User entered 'No (N)'	System	01 Apr 2021 17:59:30

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-04-01T11:59:27-06:00', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'a13fa576-1f89-4509-920f-8bef1a927b3d'	System	01 Apr 2021 17:59:30
User entered '01 Apr 2021 11:59:27'	System	01 Apr 2021 17:59:30

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-04-06T12:00:15-06:00', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '361fb4d1-f37d-472e-a8a0-606baafa4c58'	System	06 Apr 2021 18:00:25
User entered 'No (N)'	System	06 Apr 2021 18:00:25

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

Have you been exposed to someone with 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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-04-06T12:00:18-06:00', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '361fb4d1-f37d-472e-a8a0-606baafa4c58'	System	06 Apr 2021 18:00:25
User entered 'No (N)'	System	06 Apr 2021 18:00:25

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-04-06T12:00:22-06:00', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '361fb4d1-f37d-472e-a8a0-606baafa4c58'	System	06 Apr 2021 18:00:25
User entered '06 Apr 2021 12:00:22'	System	06 Apr 2021 18:00:25



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-04-14T18:12:51-06:00', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '66c41186-6eb3-4819-9255-d5a1fc4f8997' User entered 'No (N)'	System	15 Apr 2021 00:13:00
	System	15 Apr 2021 00:13:00

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

Have you been exposed to someone with 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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-04-14T18:12:53-06:00', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '66c41186-6eb3-4819-9255-d5a1fc4f8997'	System	15 Apr 2021 00:13:00
User entered 'No (N)'	System	15 Apr 2021 00:13:00

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-04-14T18:12:57-06:00', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '66c41186-6eb3-4819-9255-d5a1fc4f8997'	System	15 Apr 2021 00:13:00
User entered '14 Apr 2021 18:12:57'	System	15 Apr 2021 00:13:00

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 07:34:27



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-04-21T10:06:05-06:00', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'df1cda39-e227-47a0-8f8d-028b607e7b38'	System	21 Apr 2021 16:10:14
User entered 'No (N)'	System	21 Apr 2021 16:10:14

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

Have you been exposed to someone with 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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-04-21T10:06:08-06:00', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'df1cda39-e227-47a0-8f8d-028b607e7b38'	System	21 Apr 2021 16:10:14
User entered 'No (N)'	System	21 Apr 2021 16:10:14

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-04-21T10:06:15-06:00', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'df1cda39-e227-47a0-8f8d-028b607e7b38'	System	21 Apr 2021 16:10:14
User entered '21 Apr 2021 10:06:15'	System	21 Apr 2021 16:10:14

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-04-27T12:00:14-06:00', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '96acadf9-45c9-471b-a22d-4bfdb1b0c3eb' User entered 'No (N)'	System	29 Apr 2021 05:36:46
	System	29 Apr 2021 05:36:46



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

Have you been exposed to someone with 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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-04-27T12:00:16-06:00', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '96acadf9-45c9-471b-a22d-4bfdb1b0c3eb' User entered 'No (N)'	System	29 Apr 2021 05:36:46
	System	29 Apr 2021 05:36:46

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-04-27T12:00:19-06:00', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: '96acadf9-45c9-471b-a22d-4bfdb1b0c3eb' User entered '27 Apr 2021 12:00:19'	System	29 Apr 2021 05:36:46
	System	29 Apr 2021 05:36:46

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-05-02T17:02:07-06:00', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'f0cd2d4d-a321-4da5-a624-b12c88984656'	System	02 May 2021 23:04:04
User entered 'No (N)'	System	02 May 2021 23:04:04

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

Have you been exposed to someone with 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 (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-05-02T17:02:09-06:00', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'f0cd2d4d-a321-4da5-a624-b12c88984656'	System	02 May 2021 23:04:04
User entered 'No (N)'	System	02 May 2021 23:04:04

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-05-02T17:02:12-06:00', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'f0cd2d4d-a321-4da5-a624-b12c88984656'	System	02 May 2021 23:04:04
User entered '02 May 2021 17:02:12'	System	02 May 2021 23:04:04



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 07:34:27



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 07:34:27



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 07:34:27



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 07:34:27



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 07:34:27



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 07:34:27



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 07:34:27



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 07:34:27



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 07:34:27



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 07:34:27



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 07:34:27



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 07:34:27



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 07:34:27



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 07:34:27



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 07:34:27



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 07:34:27



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 07:34:27



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 07:34:27



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 07:34:27



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 07:34:27



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 07:34:27



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 07:34:27



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 07:34:27



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 07:34:27



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 07:34:27



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 07:34:27



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 07:34:27



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 07:34:27



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 07:34:27



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 07:34:27



**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 07:34:27

**US3502142**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:57:35**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:34:27
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 07:34:27

US3502142

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 07:57:35

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-03-02T20:40:36-07:00', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'e509b8b1-49e7-4097-b8fa-99c2d68f74b7'	System	03 Mar 2021 03:40:46
User entered 'No (N)'	System	03 Mar 2021 03:40:46

**US3502142**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:31:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (803D3BF5-55B3-4D90-A296-475E7C0DAFFC)', Time: '2021-03-02T20:40:40-07:00', User OID: 'PatientReportedOutcome (US3502142)', ODM File OID: 'e509b8b1-49e7-4097-b8fa-99c2d68f74b7'	System	03 Mar 2021 03:40:46
User entered '02 Mar 2021 20:40:40'	System	03 Mar 2021 03:40:46

**US3502142**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	Laurel Ware (b) (4)	11 Feb 2021 22:56:29

**US3502142**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '04 Dec 2020'	Laurel Ware (b) (4)	11 Feb 2021 22:56:29

**US3502142**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Contact Made (CONTACT MADE)'	Laurel Ware (b) (4)	11 Feb 2021 22:56:29

**US3502142**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	Laurel Ware (b) (4)	11 Feb 2021 22:56:29



**US3502142**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:35**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	Laurel Ware (b) (4)	11 Feb 2021 22:56:41

**US3502142**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 17:51:00
User entered 'I'	System	11 Feb 2021 22:56:41

**US3502142**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:37:06
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'No (N)'	Laurel Ware (b) (4)	11 Feb 2021 22:57:09

**US3502142**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:37:06
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	Laurel Ware (b) (4)	11 Feb 2021 22:57:09

**US3502142**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:37:06
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	Laurel Ware (b) (4)	11 Feb 2021 22:57:09

**US3502142**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:37:06
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'pt in clinic for decision visit 1/8/21'	Laurel Ware (b) (4)	11 Feb 2021 22:57:09

**US3502142**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:35**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:37:06
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	Laurel Ware (b) (4)	11 Feb 2021 22:57:16

**US3502142**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:37:06
User entered 'I'	System	11 Feb 2021 22:57:16



**US3502142**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:37:06
User signature succeeded.	Thomas Campbell (b) (4)	19 Feb 2021 21:48:53
Signature has been broken.	Laurel Ware (b) (4)	17 Feb 2021 21:25:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Laurel Ware (b) (4)	17 Feb 2021 21:25:59
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'No (N)'	Laurel Ware (b) (4)	11 Feb 2021 22:57:36

**US3502142**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:37:06
User signature succeeded.	Thomas Campbell (b) (4)	19 Feb 2021 21:48:53
Signature has been broken.	Laurel Ware (b) (4)	17 Feb 2021 21:25:59
User entered '05 Feb 2021' reason for change: Data Entry Error	Laurel Ware (b) (4)	17 Feb 2021 21:25:59
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	Laurel Ware (b) (4)	11 Feb 2021 22:57:36

**US3502142**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:37:06
User signature succeeded.	Thomas Campbell (b) (4)	19 Feb 2021 21:48:53
Signature has been broken.	Laurel Ware (b) (4)	17 Feb 2021 21:25:59
User entered 'Contact Made (CONTACT MADE)'	Laurel Ware (b) (4)	17 Feb 2021 21:25:59
reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	Laurel Ware (b) (4)	11 Feb 2021 22:57:36

**US3502142**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:37:06
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'pt in clinic for decision visit 2/5/21'	Laurel Ware (b) (4)	11 Feb 2021 22:57:36

**US3502142**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:35**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:37:06
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	Laurel Ware (b) (4)	11 Feb 2021 22:57:44

**US3502142**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 13:37:06
User entered 'I'	System	11 Feb 2021 22:57:44

**US3502142**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:04
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
User entered 'Yes (Y)'	Laurel Ware (b) (4)	25 Mar 2021 17:28:04

US3502142

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:57:35

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:04
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 11:03:05
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'target date 3/8, it is within window' (Site from System).	Laurel Ware (b) (4) (b) (4)	25 Mar 2021 17:29:07
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	25 Mar 2021 17:28:04
User entered '09 Mar 2021'	Laurel Ware (b) (4) (b) (4)	25 Mar 2021 17:28:04



**US3502142**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:04
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
User entered 'Contact Made (CONTACT MADE)'	Laurel Ware (b) (4)	25 Mar 2021 17:28:04

**US3502142**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:04
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
User entered 'in for OL day 57 3/9/21'	Laurel Ware (b) (4)	25 Mar 2021 17:28:04

**US3502142**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:35**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:04
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	22 Mar 2021 20:41:57

**US3502142**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:54:04
User entered 'I'	System	22 Mar 2021 20:41:57

US3502142

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:35

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:50
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
User closed query 'Per CDM: Please complete the vital signs assessment form.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 04:33:07
Query 'Per CDM: Please complete the vital signs assessment form.' answered with 'vitals entered' (Site from DM).	Suzanne Fiorillo (b) (4)	30 Mar 2021 23:23:12
User opened query 'Per CDM: Please complete the vital signs assessment form.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 08:44:29
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	22 Mar 2021 20:42:24

US3502142

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:57:35

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:50
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
User entered '30 Mar 2021' reason for change: Data Entry Error	Suzanne Fiorillo (b) (4)	30 Mar 2021 23:21:53
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	24 Mar 2021 12:50:26
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'date is correct' (Site from System).	Suzanne Fiorillo (b) (4)	22 Mar 2021 20:42:31
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	22 Mar 2021 20:42:24
User entered '09 Mar 2021'	Suzanne Fiorillo (b) (4)	22 Mar 2021 20:42:24

**US3502142**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:57:35**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:50
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
User entered 'Clinic (Clinic)'	Suzanne Fiorillo (b) (4)	22 Mar 2021 20:42:24

**US3502142**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:57:35**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:50
User entered 'VISIT4'	System	22 Mar 2021 20:42:24



**US3502142**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:50
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	30 Mar 2021 23:22:28

**US3502142**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:50
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
User entered '30 Mar 2021'	Suzanne Fiorillo (b) (4)	30 Mar 2021 23:22:28

**US3502142**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:50
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
User entered '11:55'	Suzanne Fiorillo (b) (4)	30 Mar 2021 23:22:28

**US3502142**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:50
User entered '30 Mar 2021 11:55'	System	30 Mar 2021 23:22:28

**US3502142**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:50
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
User entered '36.2' C	Suzanne Fiorillo (b) (4)	30 Mar 2021 23:22:28

**US3502142**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:50
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
User entered 'Other (Other)'	Suzanne Fiorillo (b) (4)	30 Mar 2021 23:22:28

**US3502142**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:50
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
User entered 'temporal'	Suzanne Fiorillo (b) (4)	30 Mar 2021 23:22:28

**US3502142**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:50
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
User entered '86'	Suzanne Fiorillo (b) (4)	30 Mar 2021 23:22:28



**US3502142**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:50
User entered 'bpm'	System	30 Mar 2021 23:22:28

**US3502142**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:50
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
User entered '14'	Suzanne Fiorillo (b) (4)	30 Mar 2021 23:22:28

**US3502142**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:50
User entered 'breaths/min'	System	30 Mar 2021 23:22:28

**US3502142**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:50
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
User entered '134'	Suzanne Fiorillo (b) (4)	30 Mar 2021 23:22:28

**US3502142**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:50
User entered 'mmHg'	System	30 Mar 2021 23:22:28

**US3502142**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:50
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
User entered '87'	Suzanne Fiorillo (b) (4)	30 Mar 2021 23:22:28

**US3502142**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:50
User entered 'mmHg'	System	30 Mar 2021 23:22:28

**US3502142**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:50



**US3502142**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:50

**US3502142**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:57:35**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:50
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	22 Mar 2021 20:42:42

US3502142

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:35

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:50
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	30 Mar 2021 23:22:37
User entered '30 Mar 2021' reason for change: Data Entry Error	Suzanne Fiorillo (b) (4)	30 Mar 2021 23:22:37
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4) System	30 Mar 2021 23:21:53
User entered '09 Mar 2021'	Suzanne Fiorillo (b) (4)	22 Mar 2021 20:42:42
	(b) (4)	

**US3502142**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:57:35**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:50
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	22 Mar 2021 20:42:56

US3502142

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:35

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:50
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).	System	30 Mar 2021 23:22:54
User entered '30 Mar 2021' reason for change: Data Entry Error	Suzanne Fiorillo (b) (4)	30 Mar 2021 23:22:54
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	
User entered '09 Mar 2021'	System	30 Mar 2021 23:21:53
	Suzanne Fiorillo (b) (4)	22 Mar 2021 20:42:56
	(b) (4)	

**US3502142**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:57:35**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:50
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
User entered '12:15' reason for change: Data Entry Error	Suzanne Fiorillo (b) (4)	30 Mar 2021 23:22:54
User entered '11:10'	Suzanne Fiorillo (b) (4)	22 Mar 2021 20:42:56

**US3502142**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:57:35**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:50
User entered '30 Mar 2021 12:15'	System	30 Mar 2021 23:22:54
User entered '09 Mar 2021 11:10'	System	22 Mar 2021 20:42:56

US3502142

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:57:35

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:50
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	22 Mar 2021 20:43:01



**US3502142**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:53:50
User entered 'I'	System	22 Mar 2021 20:43:01

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:57:35**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:13:08

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:57:35**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '08 Jan 2021'	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:13:08

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:57:35**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Home (Home)'	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:13:08

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:57:35**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered 'UNBLND_DECIDE'	System	08 Jan 2021 20:13:08

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:57:35**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '08 Jan 2021'	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:13:55

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:57:35**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:11:28

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:57:35**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:13:55



**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:57:35**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:11:28

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:57:35**

**Date of unblinding** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '08 Jan 2021'	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:13:55

US3502142

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 07:57:35

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Placebo (Placebo)'	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:13:55

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:57:35**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 14:46:09
User entered 'Placebo (Placebo)'	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:13:55
	(b) (4)	

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:57:35**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 14:46:09
User entered 'Placebo (Placebo)'	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:13:55
	(b) (4)	

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:57:35**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:13:55

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:57:35**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered '1'	System	08 Jan 2021 20:13:55

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:57:35**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered 'I'	System	08 Jan 2021 20:13:55



**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 07:57:35**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered missing code ND - Not Done.	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:15:26

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 07:57:35**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered missing code ND - Not Done.	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:15:26

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 07:57:35**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered empty.	System	08 Jan 2021 20:15:26
DataPoint set to visible.	System	08 Jan 2021 20:13:55

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 07:57:35**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered missing code ND - Not Done.	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:15:26

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 07:57:35**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered missing code ND - Not Done.	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:15:26

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 07:57:35**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered empty.	System	08 Jan 2021 20:15:26
DataPoint set to visible.	System	08 Jan 2021 20:13:55

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User accepted default value 'Pre-Dose (PREDOSE)'	Suzanne Fiorillo (b) (4) (b) (4)	08 Jan 2021 20:15:26

US3502142

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:15:26



**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '08 Jan 2021'	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:15:26

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '10:25'	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:15:26

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered '08 Jan 2021 10:25'	System	08 Jan 2021 20:15:26

US3502142

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '97.2' F	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:15:26

US3502142

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Other (Other)'	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:15:26

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'temporal'	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:15:26

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '78'	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:15:26

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered 'bpm'	System	08 Jan 2021 20:15:26



US3502142

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '14'	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:15:26

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered 'breaths/min'	System	08 Jan 2021 20:15:26

US3502142

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '112'	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:15:26

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered 'mmHg'	System	08 Jan 2021 20:15:26

US3502142

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '74'	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:15:26

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered 'mmHg'	System	08 Jan 2021 20:15:26

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 07:57:35**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered missing code ND - Not Done.	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:15:26

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 07:57:35**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered missing code ND - Not Done.	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:15:26



**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 07:57:35**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered empty.	System	08 Jan 2021 20:15:26
DataPoint set to visible.	System	08 Jan 2021 20:13:55

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User accepted default value 'Post-Dose (POSTDOSE)'	Suzanne Fiorillo (b) (4) (b) (4)	08 Jan 2021 20:15:26

US3502142

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:35

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'No (N)'	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:15:26

US3502142

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:35

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:15:26

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:15:26

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered empty.	System	08 Jan 2021 20:15:26

US3502142

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:15:26

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:15:26



**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:15:26

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:15:26

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered empty.	System	08 Jan 2021 20:15:26

US3502142

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:15:26

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered empty.	System	08 Jan 2021 20:15:26

US3502142

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:15:26

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered empty.	System	08 Jan 2021 20:15:26

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:15:26



**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered empty.	System	08 Jan 2021 20:15:26

US3502142

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:57:35

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:15:47

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:57:35**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '08 Jan 2021'	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:15:47

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:57:35**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:16:09

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:57:35**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:16:09

US3502142

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:35

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)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:16:09

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:57:35**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered 'mRNA-1273'	System	08 Jan 2021 20:16:09
DataPoint set to visible.	System	08 Jan 2021 20:13:55

US3502142

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:35

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '08 Jan 2021'	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:16:09



**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:57:35**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '10:45'	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:16:09

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:57:35**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered '08 Jan 2021 10:45'	System	08 Jan 2021 20:16:09

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:57:35**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Left Arm (LEFT ARM)'	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:16:09

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:57:35**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered 'ONCE'	System	08 Jan 2021 20:16:09

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:57:35**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered 'INTRAMUSCULAR'	System	08 Jan 2021 20:16:09

US3502142

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:35

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Feb 2021 21:48:53
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:16:34

US3502142

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:57:35

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 08Jan2021 is recorded under OL-1 visit in EDC, however the same is reported under OL-1 Visit with date 06Jan2021 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).		22 Feb 2021 15:36:26
User signature succeeded.	Thomas Campbell (b) (4)	19 Feb 2021 21:48:53
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 08Jan2021 is recorded under OL-1 visit in EDC, however the same is reported under OL-1 Visit with date 06Jan2021 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with 'The correct date is 01/08/2021' (Site from DM).	(b) (4) Suzanne Fiorillo (b) (4)	17 Feb 2021 00:43:20
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 08Jan2021 is recorded under OL-1 visit in EDC, however the same is reported under OL-1 Visit with date 06Jan2021 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 14:10:46
User entered '08 Jan 2021'	Suzanne Fiorillo (b) (4) (b) (4)	08 Jan 2021 20:16:34

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:57:35**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Feb 2021 21:48:53
User entered '10:35'	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:16:34



**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:57:35**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered '08 Jan 2021 10:35'	System	08 Jan 2021 20:16:34

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 07:57:35**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Feb 2021 21:48:53
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:16:52

US3502142

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 07:57:35

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Feb 2021 21:48:53
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated "08-JAN-2021" is recorded under Participant Decision Visit/OL-D1 visit in EDC; however, in PPD portal, it is recorded as "06-JAN-2021" for OL-1 visit. Kindly review the collection date and update as appropriate, else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 09:55:44
Query 'Per GCL Lab Reconciliation: Swab: Sample dated "08-JAN-2021" is recorded under Participant Decision Visit/OL-D1 visit in EDC; however, in PPD portal, it is recorded as "06-JAN-2021" for OL-1 visit. Kindly review the collection date and update as appropriate, else clarify. ' answered with "The date 01/08/21 is correct." (Site from DM).	Suzanne Fiorillo (b) (4) (b) (4)	17 Feb 2021 00:43:58
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated "08-JAN-2021" is recorded under Participant Decision Visit/OL-D1 visit in EDC; however, in PPD portal, it is recorded as "06-JAN-2021" for OL-1 visit. Kindly review the collection date and update as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 12:17:35
User entered '08 Jan 2021'	Suzanne Fiorillo (b) (4) (b) (4)	08 Jan 2021 20:16:52

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 07:57:35**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Feb 2021 21:48:53
User entered '10:30'	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:16:52

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 07:57:35**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered '08 Jan 2021 10:30'	System	08 Jan 2021 20:16:52

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:35**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	08 Jan 2021 20:16:57

**US3502142**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered 'I'	System	08 Jan 2021 20:16:57

**US3502142**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	Laurel Ware (b) (4)	29 Jan 2021 22:42:55



**US3502142**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '15 Jan 2021'	Laurel Ware (b) (4)	29 Jan 2021 22:42:55

**US3502142**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Contact Made (CONTACT MADE)'	Laurel Ware (b) (4)	29 Jan 2021 22:42:55

**US3502142**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	Laurel Ware (b) (4)	29 Jan 2021 22:42:55

**US3502142**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:35**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	Laurel Ware (b) (4)	29 Jan 2021 22:43:00

**US3502142**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered 'I'	System	29 Jan 2021 22:43:00

**US3502142**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:35**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered 'I'	System	29 Jan 2021 22:43:00
DataPoint set to visible.	System	29 Jan 2021 22:43:00

**US3502142**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:57:35**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	05 Feb 2021 16:33:00

**US3502142**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:57:35**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '05 Feb 2021'	Suzanne Fiorillo (b) (4)	05 Feb 2021 16:33:00



**US3502142**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:57:35**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Clinic (Clinic)'	Suzanne Fiorillo (b) (4)	05 Feb 2021 16:33:00

**US3502142**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:57:35**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered 'OLD29'	System	05 Feb 2021 16:33:00

**US3502142**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User accepted default value 'Pre-Dose (PREDOSE)'	Suzanne Fiorillo (b) (4) (b) (4)	05 Feb 2021 16:35:33

**US3502142**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	05 Feb 2021 16:35:33

**US3502142**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '05 Feb 2021'	Suzanne Fiorillo (b) (4)	05 Feb 2021 16:35:33

**US3502142**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered by System	System	05 Feb 2021 17:18:38
data change (Site from System).		05 Feb 2021 17:18:38
User entered '09:20' reason for change: Data Entry Error	Suzanne Fiorillo (b) (4)	05 Feb 2021 17:18:38
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	
User entered empty.	System	05 Feb 2021 16:35:33
	Suzanne Fiorillo (b) (4)	05 Feb 2021 16:35:33
	(b) (4)	

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**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered '05 Feb 2021 09:20'	System	05 Feb 2021 17:18:38
User entered empty.	System	05 Feb 2021 16:35:33

US3502142

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered by System	System	05 Feb 2021 17:18:38
data change (Site from System).		05 Feb 2021 17:18:38
User entered '96.8' F reason for change: Data Entry Error	Suzanne Fiorillo (b) (4)	05 Feb 2021 17:18:38
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Feb 2021 16:35:33
User entered empty.	Suzanne Fiorillo (b) (4)	05 Feb 2021 16:35:33
	(b) (4)	



US3502142

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:35

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	05 Feb 2021 17:19:02
Query 'Data is required. Please provide.' answered by System data change (Site from System).		05 Feb 2021 17:19:02
User entered 'Other (Other)' reason for change: Data Entry Error	Suzanne Fiorillo (b) (4)	05 Feb 2021 17:19:02
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	05 Feb 2021 17:18:38
User entered empty.	Suzanne Fiorillo (b) (4)	05 Feb 2021 16:35:33
	(b) (4)	

**US3502142**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'temporal' reason for change: Data Entry Error	(b) (4)	
	Suzanne Fiorillo (b) (4)	05 Feb 2021 17:19:02
User entered empty.	(b) (4)	
	Suzanne Fiorillo (b) (4)	05 Feb 2021 16:35:33
	(b) (4)	

US3502142

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:35

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered by System	System	05 Feb 2021 17:18:38
data change (Site from System).		05 Feb 2021 17:18:38
User entered '66' reason for change: Data Entry Error	Suzanne Fiorillo (b) (4)	05 Feb 2021 17:18:38
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Feb 2021 16:35:33
User entered empty.	Suzanne Fiorillo (b) (4)	05 Feb 2021 16:35:33
	(b) (4)	

**US3502142**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered 'bpm'	System	05 Feb 2021 17:18:38
User entered empty.	System	05 Feb 2021 16:35:33

US3502142

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered by System	System	05 Feb 2021 17:18:38
data change (Site from System).		05 Feb 2021 17:18:38
User entered '14' reason for change: Data Entry Error	Suzanne Fiorillo (b) (4)	05 Feb 2021 17:18:38
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Feb 2021 16:35:33
User entered empty.	Suzanne Fiorillo (b) (4)	05 Feb 2021 16:35:33
	(b) (4)	

**US3502142**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered 'breaths/min'	System	05 Feb 2021 17:18:38
User entered empty.	System	05 Feb 2021 16:35:33

US3502142

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered by System	System	05 Feb 2021 17:18:38
data change (Site from System).		05 Feb 2021 17:18:38
User entered '108' reason for change: Data Entry	Suzanne Fiorillo (b) (4)	05 Feb 2021 17:18:38
Error	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Feb 2021 16:35:33
User entered empty.	Suzanne Fiorillo (b) (4)	05 Feb 2021 16:35:33
	(b) (4)	

**US3502142**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered 'mmHg'	System	05 Feb 2021 17:18:38
User entered empty.	System	05 Feb 2021 16:35:33



US3502142

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:57:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered by System	System	05 Feb 2021 17:18:38
data change (Site from System).		05 Feb 2021 17:18:38
User entered '82' reason for change: Data Entry Error	Suzanne Fiorillo (b) (4)	05 Feb 2021 17:18:38
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Feb 2021 16:35:33
User entered empty.	Suzanne Fiorillo (b) (4)	05 Feb 2021 16:35:33
	(b) (4)	

**US3502142**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered 'mmHg'	System	05 Feb 2021 17:18:38
User entered empty.	System	05 Feb 2021 16:35:33

**US3502142**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User accepted default value 'Post-Dose (POSTDOSE)'	Suzanne Fiorillo (b) (4) (b) (4)	05 Feb 2021 16:35:33

**US3502142**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	05 Feb 2021 16:35:33

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**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '05 Feb 2021'	Suzanne Fiorillo (b) (4)	05 Feb 2021 16:35:33

**US3502142**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered by System	System	05 Feb 2021 17:19:51
data change (Site from System).		05 Feb 2021 17:19:51
User entered '10:02' reason for change: Data Entry Error	Suzanne Fiorillo (b) (4)	05 Feb 2021 17:19:51
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	
User entered empty.	System	05 Feb 2021 16:35:33
	Suzanne Fiorillo (b) (4)	05 Feb 2021 16:35:33
	(b) (4)	

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**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered '05 Feb 2021 10:02'	System	05 Feb 2021 17:19:51
User entered empty.	System	05 Feb 2021 16:35:33

US3502142

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
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)	08 Feb 2021 10:33:58
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 'ncs' (Site from System).	Suzanne Fiorillo (b) (4) (b) (4)	05 Feb 2021 17:20:08
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	05 Feb 2021 17:19:51
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Feb 2021 17:19:51
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	05 Feb 2021 17:19:51
User entered '96.7' F reason for change: Data Entry Error	Suzanne Fiorillo (b) (4) (b) (4)	05 Feb 2021 17:19:51
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Feb 2021 16:35:33
User entered empty.	Suzanne Fiorillo (b) (4) (b) (4)	05 Feb 2021 16:35:33



**US3502142**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4)	05 Feb 2021 17:19:51
User entered empty.	Suzanne Fiorillo (b) (4)	05 Feb 2021 16:35:33
	(b) (4)	

**US3502142**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'temporal' reason for change: Data Entry Error	Suzanne Fiorillo (b) (4)	05 Feb 2021 17:19:51
User entered empty.	Suzanne Fiorillo (b) (4)	05 Feb 2021 16:35:33

**US3502142**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered by System	System	05 Feb 2021 17:19:51
data change (Site from System).		05 Feb 2021 17:19:51
User entered '72' reason for change: Data Entry	Suzanne Fiorillo (b) (4)	05 Feb 2021 17:19:51
Error	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Feb 2021 16:35:33
User entered empty.	Suzanne Fiorillo (b) (4)	05 Feb 2021 16:35:33
	(b) (4)	

**US3502142**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered 'bpm'	System	05 Feb 2021 17:19:51
User entered empty.	System	05 Feb 2021 16:35:33

US3502142

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:35

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Feb 2021 17:19:51
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	05 Feb 2021 17:19:51
User entered '14' reason for change: Data Entry Error	Suzanne Fiorillo (b) (4)	05 Feb 2021 17:19:51
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	05 Feb 2021 16:35:33
User entered empty.	Suzanne Fiorillo (b) (4)	05 Feb 2021 16:35:33
	(b) (4)	

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**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered 'breaths/min'	System	05 Feb 2021 17:19:51
User entered empty.	System	05 Feb 2021 16:35:33

US3502142

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:35

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered by System	System	05 Feb 2021 17:19:51
data change (Site from System).		05 Feb 2021 17:19:51
User entered '122' reason for change: Data Entry	Suzanne Fiorillo (b) (4)	05 Feb 2021 17:19:51
Error	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Feb 2021 16:35:33
User entered empty.	Suzanne Fiorillo (b) (4)	05 Feb 2021 16:35:33
	(b) (4)	

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**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered 'mmHg'	System	05 Feb 2021 17:19:51
User entered empty.	System	05 Feb 2021 16:35:33



US3502142

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:57:35

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered by System	System	05 Feb 2021 17:19:51
data change (Site from System).		05 Feb 2021 17:19:51
User entered '84' reason for change: Data Entry	Suzanne Fiorillo (b) (4)	05 Feb 2021 17:19:51
Error	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Feb 2021 16:35:33
User entered empty.	Suzanne Fiorillo (b) (4)	05 Feb 2021 16:35:33
	(b) (4)	

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**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered 'mmHg'	System	05 Feb 2021 17:19:51
User entered empty.	System	05 Feb 2021 16:35:33

**US3502142**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:57:35**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	05 Feb 2021 16:33:39

**US3502142**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:57:35**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '05 Feb 2021'	Suzanne Fiorillo (b) (4)	05 Feb 2021 16:33:39

**US3502142**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:57:35**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	05 Feb 2021 16:33:25

**US3502142**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:57:35**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	Suzanne Fiorillo (b) (4)	05 Feb 2021 16:33:25

US3502142

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:57:35

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)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	Suzanne Fiorillo (b) (4)	05 Feb 2021 16:33:25

**US3502142**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:57:35**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered 'mRNA-1273'	System	05 Feb 2021 16:33:25
DataPoint set to visible.	System	29 Jan 2021 22:43:00



**US3502142**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:57:35**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '05 Feb 2021'	Suzanne Fiorillo (b) (4)	05 Feb 2021 16:33:25

**US3502142**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:57:35**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '09:29'	Suzanne Fiorillo (b) (4)	05 Feb 2021 16:33:25

**US3502142**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:57:35**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered '05 Feb 2021 09:29'	System	05 Feb 2021 16:33:25

**US3502142**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:57:35**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Left Arm (LEFT ARM)'	Suzanne Fiorillo (b) (4)	05 Feb 2021 16:33:25

**US3502142**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:57:35**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered 'ONCE'	System	05 Feb 2021 16:33:25

**US3502142**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:57:35**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered 'INTRAMUSCULAR'	System	05 Feb 2021 16:33:25

**US3502142**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:35**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	05 Feb 2021 16:33:46

**US3502142**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered 'I'	System	05 Feb 2021 16:33:46



**US3502142**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User entered 'Yes (Y)'	Laurel Ware (b) (4)	23 Feb 2021 17:49:34

**US3502142**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User entered '12 Feb 2021'	Laurel Ware (b) (4)	23 Feb 2021 17:49:34

**US3502142**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User entered 'Contact Made (CONTACT MADE)'	Laurel Ware (b) (4)	23 Feb 2021 17:49:34

**US3502142**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:57:35**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User entered empty.	Laurel Ware (b) (4)	23 Feb 2021 17:49:34

**US3502142**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:35**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User entered 'Yes (Y)'	Laurel Ware (b) (4)	23 Feb 2021 17:49:40

**US3502142**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:57:35**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered 'I'	System	23 Feb 2021 17:49:40

**US3502142**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:57:35**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:10:02

**US3502142**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:57:35**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User entered '09 Mar 2021'	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:10:02



**US3502142**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:57:35**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User entered 'Clinic (Clinic)'	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:10:02

**US3502142**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:57:35**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered 'OLD57'	System	09 Mar 2021 23:10:02

**US3502142**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:11:13

**US3502142**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User entered '09 Mar 2021'	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:11:13

**US3502142**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User entered '10:52'	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:11:13

**US3502142**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered '09 Mar 2021 10:52'	System	09 Mar 2021 23:11:13

US3502142

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:57:35

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
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)	11 Mar 2021 03:42:10
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 'ncs' (Site from System).	Suzanne Fiorillo (b) (4) (b) (4)	09 Mar 2021 23:21:29
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	09 Mar 2021 23:11:13
User entered '35.9' C	Suzanne Fiorillo (b) (4) (b) (4)	09 Mar 2021 23:11:13

**US3502142**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User entered 'Other (Other)'	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:11:13



**US3502142**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User entered 'temporal'	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:11:13

**US3502142**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User entered '91'	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:11:13

**US3502142**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered 'bpm'	System	09 Mar 2021 23:11:13

**US3502142**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User entered '14'	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:11:13

**US3502142**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered 'breaths/min'	System	09 Mar 2021 23:11:13

**US3502142**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User entered '105'	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:11:13

**US3502142**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered 'mmHg'	System	09 Mar 2021 23:11:13

**US3502142**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User entered '66'	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:11:13



**US3502142**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered 'mmHg'	System	09 Mar 2021 23:11:13

**US3502142**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	24 Apr 2021 14:58:57

**US3502142**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:57:35**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57

**US3502142**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:57:35**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:10:12

**US3502142**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:57:35**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User entered '09 Mar 2021'	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:10:12

**US3502142**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:57:35**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:10:37

**US3502142**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:57:35**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User entered '09 Mar 2021'	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:10:37

**US3502142**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:57:35**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User entered '11:10'	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:10:37



**US3502142**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:57:35**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:58:57
User entered '09 Mar 2021 11:10'	System	09 Mar 2021 23:10:37

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 10 Jun 2021 07:57:35**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:40
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:57
User entered 'Yes (Y)'	Josie Marshall (b) (4) (b) (4)	12 Nov 2020 23:32:54

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:57:35**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
Reviewed for Safety.	(b) (4)	08 Dec 2020 17:46:12
Un-reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 17:45:54
DataPoint Verified.		17 Nov 2020 22:03:02
Reviewed for Safety.		13 Nov 2020 15:38:49
User entered 'USA-US080-2020-mRNA-1273-P301000002'	System	13 Nov 2020 15:38:44
User entered 'New'	(b) (4), (b) (6)	13 Nov 2020 15:38:44

US3502142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:35

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:03:02
User coded data point as SOC: Nervous system disorders, HLGT: Demyelinating disorders, HLT: Multiple sclerosis acute and progressive, PT: Multiple sclerosis, LLT: Multiple sclerosis - version MedDRA\\23.0.	Coder Import (b) (4)	13 Nov 2020 18:44:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	13 Nov 2020 18:44:47
Data point term sent to Coder	System	13 Nov 2020 18:43:38
Coding entries removed.	Josie Marshall (b) (4)	13 Nov 2020 18:43:19
	(b) (4)	
User entered 'multiple sclerosis' reason for change: Data Entry Error	Josie Marshall (b) (4)	13 Nov 2020 18:43:19
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Stroke - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 23:55:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	12 Nov 2020 23:55:40
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: Stroke - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 23:40:36
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	12 Nov 2020 23:40:36
Data point term sent to Coder	System	12 Nov 2020 23:39:54
User entered 'stroke'	Josie Marshall (b) (4)	12 Nov 2020 23:39:31
	(b) (4)	

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered 'Yes (Y)'	Josie Marshall (b) (4) (b) (4)	12 Nov 2020 23:39:31

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	12 Nov 2020 23:39:31

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	12 Nov 2020 23:39:31

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered '12 Nov 2020'	Josie Marshall (b) (4) (b) (4)	12 Nov 2020 23:39:31



**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered empty.	Josie Marshall (b) (4) (b) (4)	12 Nov 2020 23:39:31

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:57:35**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 23:39:31

US3502142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
	(b) (4)	
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	01 Mar 2021 20:05:24
DataPoint Un-verified.	Suzanne Fiorillo (b) (4)	01 Mar 2021 20:05:24
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Suzanne Fiorillo (b) (4)	01 Mar 2021 20:05:24
	(b) (4)	
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	01 Mar 2021 20:01:32
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered 'Yes (Y)'	Josie Marshall (b) (4)	12 Nov 2020 23:39:31
	(b) (4)	

US3502142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:35

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User entered '23 Nov 2020' reason for change: Data Entry Error	Suzanne Fiorillo (b) (4)	01 Mar 2021 20:02:58
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	01 Mar 2021 20:01:32
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	01 Mar 2021 20:01:32
DataPoint Un-verified.	Suzanne Fiorillo (b) (4)	01 Mar 2021 20:01:32
User entered '19 Nov 2020' reason for change: Data Entry Error	Suzanne Fiorillo (b) (4)	01 Mar 2021 20:01:32
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	01 Mar 2021 20:00:36
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 18:41:26
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' answered with 'Pt just started Vumerity on 12/15 and they are still doing dose escalation. ' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 20:43:11

US3502142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:35

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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)	16 Dec 2020 19:37:33
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	11 Dec 2020 19:39:24
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	11 Dec 2020 19:39:24
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	11 Dec 2020 19:38:48
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	07 Dec 2020 23:32:53
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	07 Dec 2020 23:32:53
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	07 Dec 2020 23:32:18
User closed query 'PV Query: Please provide the event end date when available.' (Site from Safety).	(b) (4), (b) (6)	27 Nov 2020 19:54:32
Query 'PV Query: Please provide the event end date when available.' answered with 'Multiple sclerosis does not have a cure; therefore, there will be no end date.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 19:23:10
User opened query 'PV Query: Please provide the event end date when available.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:16:24
DataPoint Verified.	(b) (4)	17 Nov 2020 22:03:02
User entered empty.	Josie Marshall (b) (4)	12 Nov 2020 23:39:31
	(b) (4)	

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:57:35**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered empty.	Josie Marshall (b) (4) (b) (4)	12 Nov 2020 23:39:31

US3502142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:35

[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)	29 Apr 2021 19:13:33
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 16:17:58
User entered empty.	System	12 Nov 2020 23:39:31

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered 'Grade 4 (Grade 4)'	Josie Marshall (b) (4) (b) (4)	12 Nov 2020 23:39:31



**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered 'Yes (Y)'	Josie Marshall (b) (4) (b) (4)	12 Nov 2020 23:39:31

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered '0'	Josie Marshall (b) (4) (b) (4)	12 Nov 2020 23:39:31

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered '0'	Josie Marshall (b) (4) (b) (4)	12 Nov 2020 23:39:31

US3502142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:35

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
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)	17 Nov 2020 09:20:02
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 'Not yet discharged' (Site from System).	(b) (4), (b) (6)	13 Nov 2020 00:05:19
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	12 Nov 2020 23:39:31
User entered 'I'	Josie Marshall (b) (4) (b) (4)	12 Nov 2020 23:39:31

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:57:35**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered '12 Nov 2020'	Josie Marshall (b) (4) (b) (4)	12 Nov 2020 23:39:31

US3502142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:35

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:02:18
DataPoint Un-verified.	Josie Marshall (b) (4) (b) (4)	19 Nov 2020 20:09:40
User entered '13 Nov 2020' reason for change: Data Entry Error	Josie Marshall (b) (4) (b) (4)	19 Nov 2020 20:09:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered empty.	Josie Marshall (b) (4) (b) (4)	12 Nov 2020 23:39:31

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	12 Nov 2020 23:39:31

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered empty.	Josie Marshall (b) (4) (b) (4)	12 Nov 2020 23:39:31



**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered '0'	Josie Marshall (b) (4) (b) (4)	12 Nov 2020 23:39:31

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered '0'	Josie Marshall (b) (4) (b) (4)	12 Nov 2020 23:39:31

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered '0'	Josie Marshall (b) (4) (b) (4)	12 Nov 2020 23:39:31

US3502142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:35

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User closed query 'PV Query Urgent: According to the narrative, the relationship to IP is 'Not Related'. Please amend response or provide reason for assessing as 'Not Applicable'. ' (Site from Safety). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:42:56
	(b) (4), (b) (6)	23 Nov 2020 17:02:18
Query 'PV Query Urgent: According to the narrative, the relationship to IP is 'Not Related'. Please amend response or provide reason for assessing as 'Not Applicable'. ' answered with 'corrected' (Site from Safety).	Josie Marshall (b) (4) (b) (4)	23 Nov 2020 16:47:32
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Josie Marshall (b) (4) (b) (4)	23 Nov 2020 16:47:18
User opened query 'PV Query Urgent: According to the narrative, the relationship to IP is 'Not Related'. Please amend response or provide reason for assessing as 'Not Applicable'. ' (Site from Safety). DataPoint Un-verified.	(b) (4), (b) (6)	21 Nov 2020 01:03:36
	Josie Marshall (b) (4) (b) (4)	19 Nov 2020 20:09:40
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Josie Marshall (b) (4) (b) (4)	19 Nov 2020 20:09:40
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered 'Related (RELATED)' reason for change: Data Entry Error	Josie Marshall (b) (4) (b) (4)	13 Nov 2020 18:43:19
User entered 'Not Related (NOT RELATED)'	Josie Marshall (b) (4) (b) (4)	12 Nov 2020 23:39:31

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered 'Not Related (NOT RELATED)'	Josie Marshall (b) (4) (b) (4)	12 Nov 2020 23:39:31

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered 'Not Applicable (NOT APPLICABLE)'	Josie Marshall (b) (4)	13 Nov 2020 18:58:31
reason for change: Data Entry Error	(b) (4)	
User entered 'None (NONE)'	Josie Marshall (b) (4)	12 Nov 2020 23:39:31
	(b) (4)	

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:57:35**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered '0' reason for change: Data Entry Error	Josie Marshall (b) (4)	13 Nov 2020 18:43:19
User entered '1'	(b) (4) Josie Marshall (b) (4) (b) (4)	12 Nov 2020 23:39:31

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered '1' reason for change: Data Entry Error	Josie Marshall (b) (4)	13 Nov 2020 18:43:19
User entered '0'	(b) (4) Josie Marshall (b) (4) (b) (4)	12 Nov 2020 23:39:31



**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered '0'	Josie Marshall (b) (4) (b) (4)	12 Nov 2020 23:39:31

US3502142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:35

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
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)	02 Mar 2021 14:41:33
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 'patient stable, ongoing MS, not related to study treatment.' (Site from Safety).	Suzanne Fiorillo (b) (4) (b) (4)	01 Mar 2021 20:04:25
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	Suzanne Fiorillo (b) (4) (b) (4)	01 Mar 2021 20:00:36
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)	29 Dec 2020 16:18:15
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 18:41:34
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 'Pt is still on dose escalation phase of Vumerity.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 20:47:18

US3502142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:35

[Outcome](#)

Audit	User	Time (GMT)
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)	16 Dec 2020 19:37:13
User closed query 'PV Query: As you reported that no end date or event resolution will be provided end date or event resolution since multiple sclerosis does not have a cure, please clarify if the outcome should be resolved with sequelae.' (Site from Safety).	(b) (4), (b) (6)	14 Dec 2020 14:17:42
Query 'PV Query: As you reported that no end date or event resolution will be provided end date or event resolution since multiple sclerosis does not have a cure, please clarify if the outcome should be resolved with sequelae.' answered with 'This is correct as is.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 19:39:45
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 19:39:24
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 19:38:48
User opened query 'PV Query: As you reported that no end date or event resolution will be provided end date or event resolution since multiple sclerosis does not have a cure, please clarify if the outcome should be resolved with sequelae.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 19:05:18
User closed query 'PV Query: As you reported that no end date or event resolution will be provided end date or event resolution since multiple sclerosis does not have a cure, please clarify if the outcome should be resolved with sequelae.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 17:42:54
Query 'PV Query: As you reported that no end date or event resolution will be provided end date or event resolution since multiple sclerosis does not have a cure, please clarify if the outcome should be resolved with sequelae.' answered with 'Because the AE is the diagnosis, this would be considered not resolved.' (Site from Safety).	(b) (4), (b) (6)	07 Dec 2020 23:33:16

US3502142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:35

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error DataPoint Un-verified.	(b) (4), (b) (6)	07 Dec 2020 23:32:53
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Dec 2020 23:32:18
User opened query 'PV Query: As you reported that no end date or event resolution will be provided end date or event resolution since multiple sclerosis does not have a cure, please clarify if the outcome should be resolved with sequelae. ' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 21:34:39
User closed query 'PV Query: Please provide the final event outcome, when available.' (Site from Safety).	(b) (4), (b) (6)	27 Nov 2020 19:54:37
Query 'PV Query: Please provide the final event outcome, when available.' answered with 'Multiple sclerosis does not have a cure; therefore, this will never be resolved.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 19:23:39
User opened query 'PV Query: Please provide the final event outcome, when available.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:16:45
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Josie Marshall (b) (4) (b) (4)	12 Nov 2020 23:39:31

US3502142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:35

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
	(b) (4)	
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	01 Mar 2021 20:05:02
DataPoint Un-verified.	Suzanne Fiorillo (b) (4)	01 Mar 2021 20:05:02
	(b) (4)	
User entered 'ongoing diagnosis of MS' reason for change: Data Entry Error	Suzanne Fiorillo (b) (4)	01 Mar 2021 20:05:02
	(b) (4)	
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	01 Mar 2021 20:00:36
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	11 Dec 2020 19:39:24
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	11 Dec 2020 19:38:48
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	07 Dec 2020 23:32:53
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	07 Dec 2020 23:32:18
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:02
	(b) (4)	
User entered empty.	Josie Marshall (b) (4)	12 Nov 2020 23:39:31
	(b) (4)	

US3502142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:35

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User closed query 'PV Query: Have any examinations for infection been performed (ie zoonotic pathogens)?' (Site from Safety).	(b) (4) (b) (4), (b) (6)	27 Nov 2020 19:54:56
User closed query 'PV Query: Has the subject had any recent animal bites?' (Site from Safety).	(b) (4), (b) (6)	27 Nov 2020 19:54:53
User closed query 'PV Query: Was a lumbar puncture performed with CSF analysis? If so, please provide results.' (Site from Safety).	(b) (4), (b) (6)	27 Nov 2020 19:54:50
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)	27 Nov 2020 19:54:47
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	27 Nov 2020 19:54:44
Query 'PV Query: Have any examinations for infection been performed (ie zoonotic pathogens)?' answered with 'No' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 18:40:14
Query 'PV Query: Has the subject had any recent animal bites?' answered with 'No' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 18:39:52
Query 'PV Query: Was a lumbar puncture performed with CSF analysis? If so, please provide results.' answered with 'See narrative' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 18:39:48
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Updated. Kindly respond with instruction on how to extend narrative section. Capped to 1999 characters. Will need further documentation.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 18:39:43
DataPoint Un-verified.	(b) (4), (b) (6)	25 Nov 2020 18:38:58

US3502142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:35

[Narrative](#)

Audit	User	Time (GMT)
User entered '11/12/2020: DEVELOPED ACUTE NUMBNESS ON RIGHT FACE (FOREHEAD TO NECK ON RIGHT SIDE OF NECK), EARLY IN THE MORNING OF 12-NOV-2020. SYMPTOMS IMPROVED AND UPON WAKING IN THE MORNING SYMPTOMS WERE RESOLVED. SHE WENT TO WORK AND AROUND 10:00-11:00 AM SHE HAD RETURN OF SAME SYMPTOMS AND PRESENTED TO SAINT ANTHONY'S EMERGENCY DEPARTMENT FOR EVALUATION. MRI OF BRAIN BY VERBAL REPORT SHOWS A RIGHT SIDED BRAIN STEM LESION AND OTHER MULTIFOCAL WHITE MATTER LESIONS. ADMITTING DIAGNOSIS IS STROKE VERSUS DEMYLINATING PROCESS. 11/13/2020 ADDENDUM: MRI WITH CONTRAST 11/12/2020 SHOWS ENHANCING LESIONS IN LEFT FRONTAL LOBE, LEFT PARIETAL LOBE AND LEFT VENTRAL MEDULLA SATISFYING IMAGING REQUIREMENTS FOR MULTIPLE SCLEROSIS AND RECOMMEND TREATMENT WITH SOLUMEDROL. GIVEN THE ADDITIONAL INFORMATION I HAVE UPDATED THE ADVERSE EVENT TERM TO "MULTIPLE SCLEROSIS." GIVEN THAT THIS IS A DEMYLINATING PROCESS THAT OCCURRED 5 WEEKS AFTER THE SECOND DOSE OF INVESTIGATIONAL PRODUCT, I HAVE UPDATED RELATIONSHIP TO INVESTIGATIONAL PRODUCT AS "RELATED." 11/19/2020 ADDENDUM: PARTICIPANT WAS EVALUATED BY NEUROLOGY CONSULT AT ROCKY MOUNTAIN MS CENTER ON 11/18/2020. THE CONSULTING NEUROLOGIST BELIEVES THAT THE PARTICIPANT HAS HAD A FIRST CLINICAL ATTACK OF MS AND THT IT IS NOT RELATED TO STUDY TREATMENT. SINCE THE CONSULTING NEUROLOGIST BELIEVES THAT THE MS IS EXPLAINED MORE LIKELY	(b) (4), (b) (6)	25 Nov 2020 18:38:58

US3502142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:35

[Narrative](#)

Audit	User	Time (GMT)
BY OTHER CAUSES THAN BY THE VACCINE I HAVE CHANGED RELATIONSHIP TO IP AS "NOT RELATED."  11/23/2020: Lumbar Puncture with CSF Interpretation. Interpretation: Isoelectric focusing/immunofixation reveals two or more unique bands in the CSF but no bands in the serum. C/w intrathecal synthesis of immunoglobulin and considered to be positive result of oligoclonal bands. Oligoclonal bands are present in ~95% of pts with MS but may be present in CSF of other neuro disease. Increased concentrations of IgG important indicator to MS but could be a/w with increased permeability of blood-CSF barrier.' reason for change: Data Entry Error		
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 'Negative COVID PCR upon hospitalization on 11/12/2020' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 18:21:01
User closed query 'PV Query: Please send a hospital discharge summary and any neurology consultation notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 17:41:50
Query 'PV Query: Please send a hospital discharge summary and any neurology consultation notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'An email was sent on 11/24/2020.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 20:43:07
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:02:18
User opened query 'PV Query: Have any examinations for infection been performed (ie zoonotic pathogens)?' (Site from Safety).		20 Nov 2020 17:22:39
User opened query 'PV Query: Has the subject had any recent animal bites?' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:22:28
PRODUCTION RELEASE (v12.003 EAB) (1725)		1847 of 2329



US3502142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:35

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Was a lumbar puncture performed with CSF analysis? If so, please provide results.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:22:16
User opened query 'PV Query: Please send a hospital discharge summary and any neurology consultation notes with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:21:43
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)	20 Nov 2020 17:16:54
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 17:16:34
DataPoint Un-verified.	Josie Marshall (b) (4) (b) (4)	19 Nov 2020 20:14:01

US3502142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:35

[Narrative](#)

Audit	User	Time (GMT)
User entered '11/12/2020: DEVELOPED ACUTE NUMBNESS ON RIGHT FACE (FOREHEAD TO NECK ON RIGHT SIDE OF NECK), EARLY IN THE MORNING OF 12-NOV-2020. SYMPTOMS IMPROVED AND UPON WAKING IN THE MORNING SYMPTOMS WERE RESOLVED. SHE WENT TO WORK AND AROUND 10:00-11:00 AM SHE HAD RETURN OF SAME SYMPTOMS AND PRESENTED TO SAINT ANTHONY'S EMERGENCY DEPARTMENT FOR EVALUATION. MRI OF BRAIN BY VERBAL REPORT SHOWS A RIGHT SIDED BRAIN STEM LESION AND OTHER MULTIFOCAL WHITE MATTER LESIONS. ADMITTING DIAGNOSIS IS STROKE VERSUS DEMYLINATING PROCESS. 11/13/2020 ADDENDUM: MRI WITH CONTRAST 11/12/2020 SHOWS ENHANCING LESIONS IN LEFT FRONTAL LOBE, LEFT PARIETAL LOBE AND LEFT VENTRAL MEDULLA SATISFYING IMAGING REQUIREMENTS FOR MULTIPLE SCLEROSIS AND RECOMMEND TREATMENT WITH SOLUMEDROL. GIVEN THE ADDITIONAL INFORMATION I HAVE UPDATED THE ADVERSE EVENT TERM TO "MULTIPLE SCLEROSIS." GIVEN THAT THIS IS A DEMYLINATING PROCESS THAT OCCURRED 5 WEEKS AFTER THE SECOND DOSE OF INVESTIGATIONAL PRODUCT, I HAVE UPDATED RELATIONSHIP TO INVESTIGATIONAL PRODUCT AS "RELATED." 11/19/2020 Addendum: Participant was evaluated by neurology consult at rocky mountain ms center on 11/18/2020. The consulting neurologist believes that the participant has had a first clinical attack of ms and tht it is not related to study treatment. Since the consulting neurologist believes that the ms is explained more likely by other causes than by the vaccine I have changed relationship to IP as "not related." reason for change: Data Entry Error	Josie Marshall (b) (4)	19 Nov 2020 20:14:01

PRODUCTION RELEASE (v12.003  
EAB) (1725)

1849 of 2329

US3502142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:35

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered '11/12/2020: DEVELOPED ACUTE NUMBNESS ON RIGHT FACE (FOREHEAD TO NECK ON RIGHT SIDE OF NECK), EARLY IN THE MORNING OF 12-NOV-2020. SYMPTOMS IMPROVED AND UPON WAKING IN THE MORNING SYMPTOMS WERE RESOLVED. SHE WENT TO WORK AND AROUND 10:00-11:00 AM SHE HAD RETURN OF SAME SYMPTOMS AND PRESENTED TO SAINT ANTHONY'S EMERGENCY DEPARTMENT FOR EVALUATION. MRI OF BRAIN BY VERBAL REPORT SHOWS A RIGHT SIDED BRAIN STEM LESION AND OTHER MULTIFOCAL WHITE MATTER LESIONS. ADMITTING DIAGNOSIS IS STROKE VERSUS DEMYLINATING PROCESS. 11/13/2020 ADDENDUM: MRI WITH CONTRAST 11/12/2020 SHOWS ENHANCING LESIONS IN LEFT FRONTAL LOBE, LEFT PARIETAL LOBE AND LEFT VENTRAL MEDULLA SATISFYING IMAGING REQUIREMENTS FOR MULTIPLE SCLEROSIS AND RECOMMEND TREATMENT WITH SOLUMEDROL. GIVEN THE ADDITIONAL INFORMATION I HAVE UPDATED THE ADVERSE EVENT TERM TO "MULTIPLE SCLEROSIS." GIVEN THAT THIS IS A DEMYLINATING PROCESS THAT OCCURRED 5 WEEKS AFTER THE SECOND DOSE OF INVESTIGATIONAL PRODUCT, I HAVE UPDATED RELATIONSHIP TO INVESTIGATIONAL PRODUCT AS "RELATED."' reason for change: Data Entry Error	Josie Marshall (b) (4)	13 Nov 2020 18:44:42

US3502142

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:57:35

[Narrative](#)

Audit	User	Time (GMT)
User entered '11/12/2020: DEVELOPED ACUTE NUMBNESS ON RIGHT FACE (FOREHEAD TO NECK ON RIGHT SIDE OF NECK), EARLY IN THE MORNING OF 12-NOV-2020. SYMPTOMS IMPROVED AND UPON WAKING IN THE MORNING SYMPTOMS WERE RESOLVED. SHE WENT TO WORK AND AROUND 10:00-11:00 AM SHE HAD RETURN OF SAME SYMPTOMS AND PRESENTED TO SAINT ANTHONY'S EMERGENCY DEPARTMENT FOR EVALUATION. MRI OF BRAIN BY VERBAL REPORT SHOWS A RIGHT SIDED BRAIN STEM LESION AND OTHER MULTIFOCAL WHITE MATTER LESIONS. ADMITTING DIAGNOSIS IS STROKE VERSUS DEMYLINATING PROCESS. 11/13/2020 Addendum: MRI with contrast 11/12/2020 shows enhancing lesions in left frontal lobe, left parietal lobe and left ventral medulla satisfying imaging requirements for multiple sclerosis and recommend treatment with solumedrol. Given the additional information I have updated the adverse event term to "multiple sclerosis." Given that this is a demylinating process that occurred 5 weeks after the second dose of investigational product, I have updated relationship to investigational product as :related.'" reason for change: Data Entry Error	Josie Marshall (b) (4)	13 Nov 2020 18:43:19
User entered 'Developed acute numbness on right face (forehead to neck on right side of neck), early in the morning of 12-nov-2020. symptoms improved and upon waking in the morning symptoms were resolved. She went to work and around 10:00-11:00 AM she had return of same symptoms and presented to saint anthony's emergency department for evaluation. MRI of brain by verbal report shows a right sided brain stem lesion and other multifocal white matter lesions. Admitting diagnosis is stroke versus demylinating process.'	Josie Marshall (b) (4)	12 Nov 2020 23:39:31

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Nov 2020 23:39:31

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Nov 2020 23:39:31

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Nov 2020 23:39:31

US3502142

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:35

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 21:59:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 21:59:51
Data point term sent to Coder	System	17 Nov 2020 21:59:13
User entered 'vitamin d deficiency'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:59:06



**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:59:06

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:59:06

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:59:06

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered '12 Nov 2020'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:59:06

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered empty.	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:59:06

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:57:35**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 21:59:06

US3502142

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:35

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 07:59:54
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'ongoing' (Site from DM).	Suzanne Fiorillo (b) (4) (b) (4)	01 Mar 2021 20:06:03
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update applicable details as appropriate. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 11:29:00
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered 'Yes (Y)'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:59:06

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:57:35**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered empty.	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:59:06



**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:57:35**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered empty.	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:59:06

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:57:35**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 21:59:06

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:59:06

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:59:06

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered '0'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:59:06

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered '0'	Josie Marshall (b) (4)	17 Nov 2020 21:59:06
	(b) (4)	

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered '0'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:59:06

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:57:35**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered empty.	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:59:06



**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:57:35**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered empty.	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:59:06

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered empty.	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:59:06

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered empty.	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:59:06

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered '0'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:59:06

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered '0'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:59:06

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered '0'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:59:06

US3502142

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:57:35

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 17:02:18
User closed query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' (Site from DM).		20 Nov 2020 06:23:05
Query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' answered with 'done' (Site from DM).	Josie Marshall (b) (4) (b) (4)	18 Nov 2020 17:28:37
DataPoint Un-verified.	Josie Marshall (b) (4) (b) (4)	18 Nov 2020 17:28:29
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Josie Marshall (b) (4) (b) (4)	18 Nov 2020 17:28:29
User opened query 'Per CDM: AE started after First Dose, however both 'Relationship to Investigational Product' and 'Relationship to Study Procedure' are 'Not Applicable'. Please review and update as appropriate. Thank you ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 10:31:47
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered 'Not Applicable (NOT APPLICABLE)'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:59:06

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered 'Not Applicable (NOT APPLICABLE)'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:59:06



**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered 'Not Applicable (NOT APPLICABLE)'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:59:06

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:57:35**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered '0'	Josie Marshall (b) (4)	17 Nov 2020 21:59:06
	(b) (4)	

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered 'I'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:59:06

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered '0'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:59:06

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:59:06

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:57:35**

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered empty.	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:59:06

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:02
User entered empty.	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:59:06

**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Nov 2020 21:59:06



**US3502142**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Nov 2020 21:59:06

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 10 Jun 2021 07:57:35**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:40
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 17:24:54

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:57:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VENLAFAXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 17:27:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 17:27:51
Data point term sent to Coder	System	15 Sep 2020 17:26:31
User entered 'Venlafaxine'	(b) (4), (b) (6)	15 Sep 2020 17:26:11

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:26:11

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'Hot flashes'	(b) (4), (b) (6)	15 Sep 2020 17:26:11

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered '37.5'	(b) (4), (b) (6)	15 Sep 2020 17:26:11

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Sep 2020 17:26:11

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:57:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:26:11



US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:57:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'once daily (QD)'	(b) (4), (b) (6)	15 Sep 2020 17:26:11

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:57:35**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:26:11

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	15 Sep 2020 17:26:11

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:57:35**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:26:11

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'UN UNK 2016'	(b) (4), (b) (6)	15 Sep 2020 17:26:11

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 17:26:11

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 17:26:11

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:57:35**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 17:26:11



**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 17:26:11

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 17:26:11

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Sep 2020 17:26:11

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Sep 2020 17:26:11

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:57:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:57:13
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
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)	17 Nov 2020 22:18:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 22:18:52
Data point term sent to Coder	System	17 Nov 2020 22:03:17
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:17
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)	03 Nov 2020 21:28:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 21:28:25
Data point term sent to Coder	System	03 Nov 2020 21:12:33
User entered 'Flu Vaccine'	(b) (4), (b) (6)	03 Nov 2020 21:11:43

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:57:13
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 21:11:43

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:57:13
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'Flu Prevention'	(b) (4), (b) (6)	03 Nov 2020 21:11:43

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:57:13
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered '0.5'	(b) (4), (b) (6)	03 Nov 2020 21:11:43



**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:57:13
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'mg (mg)'	(b) (4), (b) (6)	03 Nov 2020 21:11:43

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:57:35**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:57:13
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 21:11:43

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:57:13
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'once (ONCE)'	(b) (4), (b) (6)	03 Nov 2020 21:11:43

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:57:35**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:57:13
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 21:11:43

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:57:13
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	03 Nov 2020 21:11:43

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:57:35**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:57:13
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 21:11:43

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:57:13
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered '26 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 21:11:43

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:57:13
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered '0'	(b) (4), (b) (6)	03 Nov 2020 21:11:43



**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:57:13
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 21:11:43

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:57:35**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:57:13
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered '26 Oct 2020'	(b) (4), (b) (6)	03 Nov 2020 21:11:43

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:57:13
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'No (N)'	(b) (4), (b) (6)	03 Nov 2020 21:11:43

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:57:13
User entered empty.	System	03 Nov 2020 21:11:43

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:57:13
User entered empty.	System	03 Nov 2020 21:11:43

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 14:57:13
User entered empty.	System	03 Nov 2020 21:11:43

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:57:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:38:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE SODIUM SUCCINATE, PRODUCTSYNONYM: SOLUMEDROL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Nov 2020 22:03:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4)	17 Nov 2020 22:03:53
Data point term sent to Coder	System	17 Nov 2020 22:03:17
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE SODIUM SUCCINATE, PRODUCTSYNONYM: SOLUMEDROL - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	14 Nov 2020 05:13:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4)	14 Nov 2020 05:13:41
Data point term sent to Coder	System	13 Nov 2020 21:57:09
User entered 'solumedrol'	Josie Marshall (b) (4)	13 Nov 2020 21:56:29

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:57:35**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:38:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'No (N)'	Josie Marshall (b) (4)	13 Nov 2020 21:56:29



**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:57:35**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:38:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'multiple sclerosis'	Josie Marshall (b) (4)	13 Nov 2020 21:56:29

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:57:35**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:38:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered '1000'	Josie Marshall (b) (4)	13 Nov 2020 21:56:29

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:57:35**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:38:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'mg (mg)'	Josie Marshall (b) (4)	13 Nov 2020 21:56:29

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:57:35**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:38:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered empty.	Josie Marshall (b) (4)	13 Nov 2020 21:56:29

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:57:35**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:38:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'once daily (QD)'	Josie Marshall (b) (4) (b) (4)	13 Nov 2020 21:56:29

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:57:35**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:38:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered empty.	Josie Marshall (b) (4)	13 Nov 2020 21:56:29

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:57:35**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:38:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'Intravenous (INTRAVENOUS)'	Josie Marshall (b) (4)	13 Nov 2020 21:56:29

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:57:35**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:38:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered empty.	Josie Marshall (b) (4) (b) (4)	13 Nov 2020 21:56:29



**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:57:35**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:38:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered '12 Nov 2020'	Josie Marshall (b) (4)	13 Nov 2020 21:56:29

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:57:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:38:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered '0'	Josie Marshall (b) (4)	13 Nov 2020 21:56:29

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:57:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:38:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 21:56:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Nov 2020 21:56:41
User entered 'No (N)' reason for change: Data Entry Error	Josie Marshall (b) (4) (b) (4)	13 Nov 2020 21:56:41
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Nov 2020 21:56:29
User entered empty.	Josie Marshall (b) (4) (b) (4)	13 Nov 2020 21:56:29

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:57:35**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:38:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered '13 Nov 2020'	Josie Marshall (b) (4)	13 Nov 2020 21:56:29

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:57:35**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:38:57
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'No (N)'	Josie Marshall (b) (4)	13 Nov 2020 21:56:29

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:57:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:38:57
User entered '1'	System	13 Nov 2020 21:56:29

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:57:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:38:57
User entered '1'	System	13 Nov 2020 21:56:29

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:57:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:38:57
User entered '804 (804)'	System	13 Nov 2020 21:56:29



US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:57:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:39:01
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: METHYLPREDNISOLONE SODIUM SUCCINATE, PRODUCTSYNONYM: SOLUMEDROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 07:34:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 07:34:01
Data point term sent to Coder	System	17 Nov 2020 22:03:17
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:17
Data point term sent to Coder	System	17 Nov 2020 21:45:57
User entered 'solumedrol'	Josie Marshall (b) (4)	17 Nov 2020 21:45:34

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:57:35**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:39:01
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'No (N)'	Josie Marshall (b) (4)	17 Nov 2020 21:45:34

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:57:35**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:39:01
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'multiple sclerosis'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:45:34

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:57:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:39:01
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for the given route of this medication. Please update either DOSE or ROUTE as appropriate or provide comment for alternate dosage.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 07:51:53
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for the given route of this medication. Please update either DOSE or ROUTE as appropriate or provide comment for alternate dosage.' answered with 'dose and route are correct.' (Site from DM).	Suzanne Fiorillo (b) (4) (b) (4)	01 Mar 2021 19:40:39
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for the given route of this medication. Please update either DOSE or ROUTE as appropriate or provide comment for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 02:14:10
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered '1000'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:45:34

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:57:35**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:39:01
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'mg (mg)'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:45:34

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:57:35**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:39:01
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered empty.	Josie Marshall (b) (4)	17 Nov 2020 21:45:34

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:57:35**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:39:01
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'once daily (QD)'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:45:34

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:57:35**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:39:01
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered empty.	Josie Marshall (b) (4)	17 Nov 2020 21:45:34



US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:57:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:39:01
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Dec 2020 13:59:46
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'PO is correct per medical records. ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 20:37:18
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 12:36:04
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'Oral (ORAL)'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:45:34

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:57:35**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:39:01
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered empty.	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:45:34

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:57:35**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:39:01
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered '14 Nov 2020'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:45:34

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:57:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:39:01
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered '0'	Josie Marshall (b) (4)	17 Nov 2020 21:45:34

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:57:35**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:39:01
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:45:34

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:57:35**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:39:01
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered '16 Nov 2020'	Josie Marshall (b) (4)	17 Nov 2020 21:45:34

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:57:35**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:39:01
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'No (N)'	Josie Marshall (b) (4)	17 Nov 2020 21:45:34

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:57:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:39:01
User entered '1'	System	17 Nov 2020 21:45:34



**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:57:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:39:01
User entered '1'	System	17 Nov 2020 21:45:34

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:57:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:39:01
User entered '804 (804)'	System	17 Nov 2020 21:45:34

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:57:35

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 07:37:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 07:37:02
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	17 Nov 2020 22:03:17
Data point term sent to Coder User entered 'omeprazole'	System Josie Marshall (b) (4)	17 Nov 2020 21:46:59

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:57:35**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'Yes (Y)'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:46:39

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:57:35**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'prevent steroid induced ulcers'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:46:39

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:57:35**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered '40'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:46:39

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:57:35**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'mg (mg)'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:46:39

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:57:35**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered empty.	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:46:39



US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:57:35

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'once daily (QD)'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:46:39

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:57:35**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered empty.	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:46:39

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:57:35**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'Oral (ORAL)'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:46:39

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:57:35**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered empty.	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:46:39

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:57:35**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered '12 Nov 2020'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:46:39

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:57:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered '0'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:46:39

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:57:35**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'Yes (Y)'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:46:39

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:57:35**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered empty.	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:46:39



**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:57:35**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:46:39

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:57:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 21:46:39

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:57:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 21:46:39

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:57:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Nov 2020 21:46:39

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:57:35

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: ERGOCALCIFEROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 22:03:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 22:03:50
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	17 Nov 2020 22:03:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: ERGOCALCIFEROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 21:48:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 21:48:52
Data point term sent to Coder User entered 'ergocalciferol'	System Josie Marshall (b) (4)	17 Nov 2020 21:48:00 17 Nov 2020 21:47:46

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:57:35**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:47:46

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:57:35**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'vitamin d deficiency'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:47:46

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:57:35**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered '50000'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:47:46



**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:57:35**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'IU (IU)'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:47:46

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:57:35**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered empty.	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:47:46

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:57:35**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'every week (QS)'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:47:46

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:57:35**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered empty.	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:47:46

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:57:35**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'Oral (ORAL)'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:47:46

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:57:35**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered empty.	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:47:46

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:57:35**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered '12 Nov 2020'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:47:46

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:57:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered '0'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:47:46



**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:57:35**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'Yes (Y)'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:47:46

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:57:35**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered empty.	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:47:46

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:57:35**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:47:46

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:57:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 21:47:46

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:57:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 21:47:46

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:57:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	17 Nov 2020 21:47:46

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:57:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 22:03:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 22:03:51
Data point term sent to Coder DataPoint Verified.	System (b) (4), (b) (6)	17 Nov 2020 22:03:18 17 Nov 2020 22:03:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 21:49:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Nov 2020 21:49:52
Data point term sent to Coder User entered 'vitamin D'	System Josie Marshall (b) (4)	17 Nov 2020 21:49:02 17 Nov 2020 21:48:45

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:57:35**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:48:45



**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:57:35**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'vitamin d deficiency'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:48:45

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:57:35**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered '1000'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:48:45

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:57:35**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'IU (IU)'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:48:45

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:57:35**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered empty.	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:48:45

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:57:35**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'once daily (QD)'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:48:45

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:57:35**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered empty.	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:48:45

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:57:35**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'Oral (ORAL)'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:48:45

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:57:35**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered empty.	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:48:45



**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:57:35**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered '14 Nov 2020'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:48:45

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:57:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered '0'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:48:45

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:57:35**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'Yes (Y)'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:48:45

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:57:35**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered empty.	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:48:45

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:57:35**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:48:45

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:57:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 21:48:45

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:57:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 21:48:45

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:57:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Nov 2020 21:48:45



US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:57:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 07:20:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 07:20:01
Data point term sent to Coder	System	17 Nov 2020 22:03:18
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:03:17
Data point term sent to Coder	System	17 Nov 2020 21:50:04
User entered 'calcium'	Josie Marshall (b) (4)	17 Nov 2020 21:49:13

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:57:35**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:49:13

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:57:35**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'vitamin d deficiency'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:49:13

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:57:35**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered '500'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:49:13

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:57:35**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'mg (mg)'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:49:13

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:57:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered empty.	Josie Marshall (b) (4)	17 Nov 2020 21:49:13
	(b) (4)	

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:57:35**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'once daily (QD)'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:49:13

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:57:35**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered empty.	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:49:13



**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:57:35**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'Oral (ORAL)'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:49:13

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:57:35**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered empty.	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:49:13

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:57:35**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered '14 Nov 2020'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:49:13

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:57:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered '0'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:49:13

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:57:35**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'Yes (Y)'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:49:13

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:57:35**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered empty.	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:49:13

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:57:35**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:03:17
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	17 Nov 2020 21:49:13

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:57:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 21:49:13



**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:57:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Nov 2020 21:49:13

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:57:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Nov 2020 21:49:13

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:35

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:35:48
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE RGE (CHO), PRODUCTSYNONYM: SHINGRIX - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Mar 2021 07:27:59
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 07:27:59
User closed query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 03:45:25
Data point term sent to Coder	System	09 Mar 2021 23:14:23
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Mar 2021 23:14:19
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Mar 2021 23:14:19
User entered 'shingrix (second dose)' reason for change: Data Entry Error	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:14:19
Data point term sent to Coder	System	09 Mar 2021 23:12:22
DataPoint activated with code reason code Data required.	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:12:01
Data point term sent to Coder	System	01 Mar 2021 19:28:43
DataPoint inactivated with code reason code Data not required.	Suzanne Fiorillo (b) (4)	01 Mar 2021 19:28:21
Query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) ' answered with 'never started vumerity. MS diagnosis was after screen/enrollment date.' (Site from DM).	Suzanne Fiorillo (b) (4)	01 Mar 2021 19:28:07
Data point term sent to Coder	System	01 Mar 2021 19:26:41

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2034 of 2329

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:35

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Mar 2021 19:26:13
User entered empty; reason for change Data Entry Error	Suzanne Fiorillo (b) (4)	01 Mar 2021 19:26:13
User opened query 'Per MM: Please confirm this medication does not meet exclusion criteria #12 (Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening) (Site from DM).	(b) (4)	09 Feb 2021 11:25:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, PRODUCT: DIROXIMEL FUMARATE, PRODUCTSYNONYM: VUMERITY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Dec 2020 21:33:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Dec 2020 21:33:46
Data point term sent to Coder	System	21 Dec 2020 20:48:30
User entered 'Vumerity'	(b) (4), (b) (6)	21 Dec 2020 20:48:13

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:35

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:35:48
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
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	09 Mar 2021 23:14:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:14:19
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:12:01
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	Suzanne Fiorillo (b) (4)	01 Mar 2021 19:28:21
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 19:26:13
		21 Dec 2020 20:48:13

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:35

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:35:48
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
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	09 Mar 2021 23:14:19
User entered 'shingles prevention' reason for change: Data Entry Error	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:14:19
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:12:01
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	Suzanne Fiorillo (b) (4)	01 Mar 2021 19:28:21
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered 'Multiple sclerosis'	(b) (4), (b) (6)	21 Dec 2020 20:48:13

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:35

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:35:48
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
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	09 Mar 2021 23:14:19
User entered '50' reason for change: Data Entry Error	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:14:19
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:12:01
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	Suzanne Fiorillo (b) (4)	01 Mar 2021 19:28:21
User entered '462'	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 19:26:13
		21 Dec 2020 20:48:13

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:35

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:35:48
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
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	09 Mar 2021 23:14:19
User entered 'ug (ug)' reason for change: Data Entry Error	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:14:19
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:12:01
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	Suzanne Fiorillo (b) (4)	01 Mar 2021 19:28:21
User entered 'mg (mg)'	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 19:26:13
		21 Dec 2020 20:48:13



US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:35

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:35:48
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint activated with code reason code Data required.	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:12:01
DataPoint inactivated with code reason code Data not required.	Suzanne Fiorillo (b) (4)	01 Mar 2021 19:28:21
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 20:48:13

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:35

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:35:48
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
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	09 Mar 2021 23:14:19
User entered 'once (ONCE)' reason for change: Data Entry Error	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:14:19
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:12:01
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	Suzanne Fiorillo (b) (4)	01 Mar 2021 19:28:21
User entered 'twice daily (BID)'	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 19:26:13
		21 Dec 2020 20:48:13

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:35

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:35:48
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint activated with code reason code Data required.	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:12:01
DataPoint inactivated with code reason code Data not required.	Suzanne Fiorillo (b) (4)	01 Mar 2021 19:28:21
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 20:48:13

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:35

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:35:48
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
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	09 Mar 2021 23:14:19
User entered 'Intramuscular (INTRAMUSCULAR)' reason for change: Data Entry Error	System	09 Mar 2021 23:14:19
DataPoint activated with code reason code Data required.	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:12:01
DataPoint inactivated with code reason code Data not required.	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	Suzanne Fiorillo (b) (4)	01 Mar 2021 19:28:21
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Mar 2021 19:26:13
		21 Dec 2020 20:48:13

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:35

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:35:48
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint activated with code reason code Data required.	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:12:01
DataPoint inactivated with code reason code Data not required.	Suzanne Fiorillo (b) (4)	01 Mar 2021 19:28:21
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 20:48:13

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:35:48
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	09 Mar 2021 23:14:19
User entered '09 Mar 2021' reason for change: Data Entry Error	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:14:19
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:12:01
	(b) (4)	
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	Suzanne Fiorillo (b) (4)	01 Mar 2021 19:28:21
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered '15 Dec 2020'	(b) (4), (b) (6)	01 Mar 2021 19:26:13
		21 Dec 2020 20:48:13

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:35

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:35:48
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
DataPoint activated with code reason code Data required.	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:12:01
DataPoint inactivated with code reason code Data not required.	Suzanne Fiorillo (b) (4)	01 Mar 2021 19:28:21
User entered '0'	(b) (4), (b) (6)	21 Dec 2020 20:48:13

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:35

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:35:48
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
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	09 Mar 2021 23:14:19
User entered 'No (N)' reason for change: Data Entry Error	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:14:19
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:12:01
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	Suzanne Fiorillo (b) (4)	01 Mar 2021 19:28:21
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 19:26:13
		21 Dec 2020 20:48:13



US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:35

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:35:48
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User entered '09 Mar 2021' reason for change: Data Entry Error	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:14:19
DataPoint activated with code reason code Data required.	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:12:01
DataPoint inactivated with code reason code Data not required.	Suzanne Fiorillo (b) (4)	01 Mar 2021 19:28:21
User entered empty.	(b) (4), (b) (6)	21 Dec 2020 20:48:13

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:35

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:35:48
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
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	09 Mar 2021 23:14:19
User entered 'No (N)' reason for change: Data Entry Error	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:14:19
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:12:01
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	Suzanne Fiorillo (b) (4)	01 Mar 2021 19:28:21
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 19:26:13
		21 Dec 2020 20:48:13

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:35

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:35:48
DataPoint activated with code reason code Data required.	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:12:01
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Suzanne Fiorillo (b) (4)	01 Mar 2021 19:28:21
	(b) (4)	
User entered empty.	System	01 Mar 2021 19:26:13
User entered '2'	System	21 Dec 2020 20:48:13

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:35

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:35:48
DataPoint activated with code reason code Data required.	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:12:01
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Suzanne Fiorillo (b) (4)	01 Mar 2021 19:28:21
	(b) (4)	
User entered empty.	System	01 Mar 2021 19:26:13
User entered '1'	System	21 Dec 2020 20:48:13

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:57:35

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:35:48
DataPoint activated with code reason code Data required.	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:12:01
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Suzanne Fiorillo (b) (4)	01 Mar 2021 19:28:21
	(b) (4)	
User entered empty.	System	01 Mar 2021 19:26:13
User entered '804 (804)'	System	21 Dec 2020 20:48:13

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:57:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE RGE (CHO), PRODUCTSYNONYM: SHINGRIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 07:28:00
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 07:28:00
Data point term sent to Coder	System	09 Mar 2021 23:15:24
User entered 'shingrix (first dose)'	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:15:19

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:57:35**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
	(b) (4)	
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:15:19
	(b) (4)	

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:57:35**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
	(b) (4)	
User entered 'shingles prevention'	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:15:19
	(b) (4)	



**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:57:35**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
	(b) (4)	
User entered '50'	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:15:19
	(b) (4)	

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:57:35**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
	(b) (4)	
User entered 'ug (ug)'	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:15:19
	(b) (4)	

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:57:35**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
	(b) (4)	
User entered empty.	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:15:19
	(b) (4)	

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:57:35**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
	(b) (4)	
User entered 'once (ONCE)'	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:15:19
	(b) (4)	

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:57:35**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
	(b) (4)	
User entered empty.	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:15:19
	(b) (4)	

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:57:35**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User entered 'Intramuscular (INTRAMUSCULAR)'	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:15:19

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:57:35**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
	(b) (4)	
User entered empty.	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:15:19
	(b) (4)	

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:57:35**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
	(b) (4)	
User entered '14 Dec 2020'	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:15:19
	(b) (4)	



**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:57:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
	(b) (4)	
User entered '0'	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:15:19
	(b) (4)	

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:57:35**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
	(b) (4)	
User entered 'No (N)'	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:15:19
	(b) (4)	

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:57:35**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
	(b) (4)	
User entered '14 Dec 2020'	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:15:19
	(b) (4)	

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:57:35**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
	(b) (4)	
User entered 'No (N)'	Suzanne Fiorillo (b) (4)	09 Mar 2021 23:15:19
	(b) (4)	

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:57:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 23:15:19

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:57:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 23:15:19

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:57:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 23:15:19

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:57:35

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, PRODUCT: DIROXIMEL FUMARATE, PRODUCTSYNONYM: VUMERITY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 23:27:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 23:27:21
Data point term sent to Coder	System	30 Mar 2021 23:25:49
User entered 'vumerity'	Suzanne Fiorillo (b) (4)	30 Mar 2021 23:25:01



**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:57:35**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
	(b) (4)	
User entered 'No (N)'	Suzanne Fiorillo (b) (4)	30 Mar 2021 23:25:01
	(b) (4)	

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:57:35**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
User entered 'multiple sclerosis'	Suzanne Fiorillo (b) (4)	30 Mar 2021 23:25:01

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:57:35**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
	(b) (4)	
User entered '231'	Suzanne Fiorillo (b) (4)	30 Mar 2021 23:25:01
	(b) (4)	

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:57:35**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
	(b) (4)	
User entered 'mg (mg)'	Suzanne Fiorillo (b) (4)	30 Mar 2021 23:25:01
	(b) (4)	

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:57:35

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
	(b) (4)	
User entered empty.	Suzanne Fiorillo (b) (4)	30 Mar 2021 23:25:01
	(b) (4)	

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:57:35**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
	(b) (4)	
User entered 'twice daily (BID)'	Suzanne Fiorillo (b) (4)	30 Mar 2021 23:25:01
	(b) (4)	

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:57:35

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
	(b) (4)	
User entered empty.	Suzanne Fiorillo (b) (4)	30 Mar 2021 23:25:01
	(b) (4)	

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:57:35**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
	(b) (4)	
User entered 'Oral (ORAL)'	Suzanne Fiorillo (b) (4)	30 Mar 2021 23:25:01
	(b) (4)	



**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:57:35**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
	(b) (4)	
User entered empty.	Suzanne Fiorillo (b) (4)	30 Mar 2021 23:25:01
	(b) (4)	

US3502142

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:57:35

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 12:08:52
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' answered with 'The med was not started at the onset of the ae, date is correct.' (Site from DM).	Suzanne Fiorillo (b) (4) (b) (4)	06 Apr 2021 15:39:19
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 11:13:11
User entered '23 Mar 2021'	Suzanne Fiorillo (b) (4) (b) (4)	30 Mar 2021 23:25:01

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:57:35**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
	(b) (4)	
User entered '0'	Suzanne Fiorillo (b) (4)	30 Mar 2021 23:25:01
	(b) (4)	

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:57:35**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
	(b) (4)	
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	30 Mar 2021 23:25:01
	(b) (4)	

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:57:35**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
	(b) (4)	
User entered empty.	Suzanne Fiorillo (b) (4)	30 Mar 2021 23:25:01
	(b) (4)	

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:57:35**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
User entered 'No (N)'	(b) (4) Suzanne Fiorillo (b) (4)	30 Mar 2021 23:25:01
	(b) (4)	

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:57:35**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	30 Mar 2021 23:25:01

**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:57:35**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Mar 2021 23:25:01



**US3502142**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:57:35**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Mar 2021 23:25:01

**US3502142**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 10 Jun 2021 07:57:35**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:40
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:29:27

US3502142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 07:57:35

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '12 Nov 2020'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:34:53

US3502142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 07:57:35

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:07:22
User closed query 'Per DM CLR: Please specify the location of MRI (e.g. MRI ON ABDOMEN, MRI ON BRAIN, etc.). Update Concomitant Procedure eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 04:32:02
Query 'Per DM CLR: Please specify the location of MRI (e.g. MRI ON ABDOMEN, MRI ON BRAIN, etc.). Update Concomitant Procedure eCRF as appropriate. ' answered with 'on brain' (Site from DM).	Suzanne Fiorillo (b) (4) (b) (4)	30 Mar 2021 23:33:59
Signature has been broken.	Suzanne Fiorillo (b) (4) (b) (4)	30 Mar 2021 23:33:37
User entered 'MRI on brain' reason for change: Data Entry Error	Suzanne Fiorillo (b) (4) (b) (4)	30 Mar 2021 23:33:37
User opened query 'Per DM CLR: Please specify the location of MRI (e.g. MRI ON ABDOMEN, MRI ON BRAIN, etc.). Update Concomitant Procedure eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 03:34:05
User signature succeeded.	Thomas Campbell (b) (4) (b) (4)	16 Feb 2021 15:50:06
User entered 'MRI'	(b) (4), (b) (6)	24 Nov 2020 21:34:53

**US3502142**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:34:53

US3502142

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 07:57:35

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 21:34:53

**US3502142**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 07:57:35**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:04:47
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '23 Nov 2020'	(b) (4), (b) (6)	24 Nov 2020 21:35:43

**US3502142**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:04:47
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Lumbar Puncture'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:35:43



**US3502142**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:04:47
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:35:43

**US3502142**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 07:57:35**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:04:47
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:35:43

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'USA-US080-2020-MRNA-1273-P301000002'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Yes (Y)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Yes (Y)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44



**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Thomas'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Campbell'	System	13 Nov 2020 15:38:44

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:35

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered '12401 E. 17th Ave 3rd Floor'	Josie Marshall (b) (4)	13 Nov 2020 17:44:51
	(b) (4)	

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:35

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered 'Aurora'	Josie Marshall (b) (4)	13 Nov 2020 17:44:51
	(b) (4)	

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'CO'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered '80045'	Josie Marshall (b) (4)	13 Nov 2020 17:44:51
	(b) (4)	



**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered 'US'	System	13 Nov 2020 15:39:08

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	02 Mar 2021 14:42:07
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
	(b) (4)	
User entered '9'	System	14 Dec 2020 14:18:35
User entered '8'	System	08 Dec 2020 17:54:25
User entered '7'	System	27 Nov 2020 19:56:17
User entered '6'	System	25 Nov 2020 17:42:32
User entered '5'	System	24 Nov 2020 15:01:46
User entered '4'	System	24 Nov 2020 13:44:00
User entered '3'	System	20 Nov 2020 14:52:34
User entered '2'	System	16 Nov 2020 14:26:58
User entered '1'	System	13 Nov 2020 15:39:08

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'USA-US080-2020-MRNA-1273-P301000002'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Yes (Y)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Yes (Y)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44



**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Thomas'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Campbell'	System	13 Nov 2020 15:38:44

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:35

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered '12401 E. 17th Ave 3rd Floor'	Josie Marshall (b) (4)	13 Nov 2020 17:44:51
	(b) (4)	

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:35

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered 'Aurora'	Josie Marshall (b) (4)	13 Nov 2020 17:44:51
	(b) (4)	

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'CO'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered '80045'	Josie Marshall (b) (4)	13 Nov 2020 17:44:51
	(b) (4)	



**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered 'US'	System	13 Nov 2020 15:39:08

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	02 Mar 2021 14:42:07
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
	(b) (4)	
User entered '9'	System	14 Dec 2020 14:18:35
User entered '8'	System	08 Dec 2020 17:54:25
User entered '7'	System	27 Nov 2020 19:56:17
User entered '6'	System	25 Nov 2020 17:42:32
User entered '5'	System	24 Nov 2020 15:01:46
User entered '4'	System	24 Nov 2020 13:44:00
User entered '3'	System	20 Nov 2020 14:52:34
User entered '2'	System	16 Nov 2020 14:26:58
User entered '1'	System	13 Nov 2020 15:39:08

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 07:57:35**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
User entered '13/Nov/2020 10:39'	System	13 Nov 2020 15:39:08

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 07:57:35

**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.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered 'I'	(b) (4), (b) (6)	13 Nov 2020 15:39:08

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered		
'USA-US080-2020-MRNA-1273-P301000002'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Yes (Y)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44



**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Yes (Y)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Thomas'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Campbell'	System	13 Nov 2020 15:38:44

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:35

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered '12401 E. 17th Ave 3rd Floor'	Josie Marshall (b) (4)	13 Nov 2020 17:44:51
	(b) (4)	

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:35

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered 'Aurora'	Josie Marshall (b) (4)	13 Nov 2020 17:44:51
	(b) (4)	



**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'CO'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered '80045'	Josie Marshall (b) (4)	13 Nov 2020 17:44:51
	(b) (4)	

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered 'US'	System	13 Nov 2020 15:39:08

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	02 Mar 2021 14:42:07
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
	(b) (4)	
User entered '9'	System	14 Dec 2020 14:18:35
User entered '8'	System	08 Dec 2020 17:54:25
User entered '7'	System	27 Nov 2020 19:56:17
User entered '6'	System	25 Nov 2020 17:42:32
User entered '5'	System	24 Nov 2020 15:01:46
User entered '4'	System	24 Nov 2020 13:44:00
User entered '3'	System	20 Nov 2020 14:52:34
User entered '2'	System	16 Nov 2020 14:26:58
User entered '1'	System	13 Nov 2020 15:39:08

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 07:57:35**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
User entered '13/Nov/2020 11:45'	Josie Marshall (b) (4) (b) (4)	13 Nov 2020 18:45:24

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 07:57:35

**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.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.		17 Nov 2020 22:02:31
User entered '0'		16 Nov 2020 14:26:58

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'USA-US080-2020-MRNA-1273-P301000002'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Yes (Y)'	System	13 Nov 2020 15:38:44



**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Yes (Y)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Thomas'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Campbell'	System	13 Nov 2020 15:38:44



US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:35

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered '12401 E. 17th Ave 3rd Floor'	Josie Marshall (b) (4)	13 Nov 2020 17:44:51
	(b) (4)	

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:35

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered 'Aurora'	Josie Marshall (b) (4)	13 Nov 2020 17:44:51
	(b) (4)	

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'CO'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered '80045'	Josie Marshall (b) (4)	13 Nov 2020 17:44:51
	(b) (4)	

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered 'US'	System	13 Nov 2020 15:39:08

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	02 Mar 2021 14:42:07
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
	(b) (4)	
User entered '9'	System	14 Dec 2020 14:18:35
User entered '8'	System	08 Dec 2020 17:54:25
User entered '7'	System	27 Nov 2020 19:56:17
User entered '6'	System	25 Nov 2020 17:42:32
User entered '5'	System	24 Nov 2020 15:01:46
User entered '4'	System	24 Nov 2020 13:44:00
User entered '3'	System	20 Nov 2020 14:52:34
User entered '2'	System	16 Nov 2020 14:26:58
User entered '1'	System	13 Nov 2020 15:39:08

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 07:57:35**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
User entered '16/Nov/2020 09:26'	System	16 Nov 2020 14:26:58

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 07:57:35

**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.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.		17 Nov 2020 22:02:31
User entered 'I'		16 Nov 2020 14:26:58



**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'USA-US080-2020-MRNA-1273-P301000002'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Yes (Y)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Yes (Y)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44



**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Thomas'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Campbell'	System	13 Nov 2020 15:38:44

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:35

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered '12401 E. 17th Ave 3rd Floor'	Josie Marshall (b) (4)	13 Nov 2020 17:44:51
	(b) (4)	

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:35

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered 'Aurora'	Josie Marshall (b) (4)	13 Nov 2020 17:44:51
	(b) (4)	

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'CO'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered '80045'	Josie Marshall (b) (4)	13 Nov 2020 17:44:51
	(b) (4)	

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered 'US'	System	13 Nov 2020 15:39:08

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	02 Mar 2021 14:42:07
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
	(b) (4)	
User entered '9'	System	14 Dec 2020 14:18:35
User entered '8'	System	08 Dec 2020 17:54:25
User entered '7'	System	27 Nov 2020 19:56:17
User entered '6'	System	25 Nov 2020 17:42:32
User entered '5'	System	24 Nov 2020 15:01:46
User entered '4'	System	24 Nov 2020 13:44:00
User entered '3'	System	20 Nov 2020 14:52:34
User entered '2'	System	16 Nov 2020 14:26:58
User entered '1'	System	13 Nov 2020 15:39:08



**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 07:57:35**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:02:28
User entered '19/Nov/2020 13:14'	Josie Marshall (b) (4) (b) (4)	19 Nov 2020 20:14:43

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 07:57:35

**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.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 13:43:41
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:02:28
User entered '0'	(b) (4), (b) (6)	20 Nov 2020 14:52:34

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'USA-US080-2020-MRNA-1273-P301000002'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Yes (Y)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Yes (Y)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44



**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Thomas'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Campbell'	System	13 Nov 2020 15:38:44

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:35

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered '12401 E. 17th Ave 3rd Floor'	Josie Marshall (b) (4)	13 Nov 2020 17:44:51
	(b) (4)	

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:35

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered 'Aurora'	Josie Marshall (b) (4)	13 Nov 2020 17:44:51
	(b) (4)	

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'CO'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered '80045'	Josie Marshall (b) (4)	13 Nov 2020 17:44:51
	(b) (4)	



**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered 'US'	System	13 Nov 2020 15:39:08

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	02 Mar 2021 14:42:07
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
	(b) (4)	
User entered '9'	System	14 Dec 2020 14:18:35
User entered '8'	System	08 Dec 2020 17:54:25
User entered '7'	System	27 Nov 2020 19:56:17
User entered '6'	System	25 Nov 2020 17:42:32
User entered '5'	System	24 Nov 2020 15:01:46
User entered '4'	System	24 Nov 2020 13:44:00
User entered '3'	System	20 Nov 2020 14:52:34
User entered '2'	System	16 Nov 2020 14:26:58
User entered '1'	System	13 Nov 2020 15:39:08

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (5)**

**Generated On: 10 Jun 2021 07:57:35**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:02:28
User entered '20/Nov/2020 14:52'	System	20 Nov 2020 14:52:34

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 07:57:35

**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.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:43:41
DataPoint Verified.		23 Nov 2020 17:02:28
User entered 'I'		20 Nov 2020 14:52:34

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'USA-US080-2020-MRNA-1273-P301000002'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Yes (Y)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44



**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Yes (Y)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Thomas'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Campbell'	System	13 Nov 2020 15:38:44

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:35

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered '12401 E. 17th Ave 3rd Floor'	Josie Marshall (b) (4) (b) (4)	13 Nov 2020 17:44:51

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:35

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered 'Aurora'	Josie Marshall (b) (4)	13 Nov 2020 17:44:51
	(b) (4)	



**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'CO'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered '80045'	Josie Marshall (b) (4)	13 Nov 2020 17:44:51
	(b) (4)	

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered 'US'	System	13 Nov 2020 15:39:08

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	02 Mar 2021 14:42:07
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
	(b) (4)	
User entered '9'	System	14 Dec 2020 14:18:35
User entered '8'	System	08 Dec 2020 17:54:25
User entered '7'	System	27 Nov 2020 19:56:17
User entered '6'	System	25 Nov 2020 17:42:32
User entered '5'	System	24 Nov 2020 15:01:46
User entered '4'	System	24 Nov 2020 13:44:00
User entered '3'	System	20 Nov 2020 14:52:34
User entered '2'	System	16 Nov 2020 14:26:58
User entered '1'	System	13 Nov 2020 15:39:08

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (6)**

**Generated On: 10 Jun 2021 07:57:35**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '24/Nov/2020 13:43'	(b) (4) System	24 Nov 2020 13:44:00

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 07:57:35

**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.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Nov 2020 17:42:20
User entered 'I'	(b) (4), (b) (6)	24 Nov 2020 13:44:00

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'USA-US080-2020-MRNA-1273-P301000002'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Yes (Y)'	System	13 Nov 2020 15:38:44



**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Yes (Y)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Thomas'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Campbell'	System	13 Nov 2020 15:38:44



US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:35

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered '12401 E. 17th Ave 3rd Floor'	Josie Marshall (b) (4)	13 Nov 2020 17:44:51
	(b) (4)	

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:35

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered 'Aurora'	Josie Marshall (b) (4)	13 Nov 2020 17:44:51
	(b) (4)	

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'CO'	System	13 Nov 2020 15:38:44

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:35

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered '80045'	Josie Marshall (b) (4)	13 Nov 2020 17:44:51
	(b) (4)	

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered 'US'	System	13 Nov 2020 15:39:08

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	02 Mar 2021 14:42:07
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
	(b) (4)	
User entered '9'	System	14 Dec 2020 14:18:35
User entered '8'	System	08 Dec 2020 17:54:25
User entered '7'	System	27 Nov 2020 19:56:17
User entered '6'	System	25 Nov 2020 17:42:32
User entered '5'	System	24 Nov 2020 15:01:46
User entered '4'	System	24 Nov 2020 13:44:00
User entered '3'	System	20 Nov 2020 14:52:34
User entered '2'	System	16 Nov 2020 14:26:58
User entered '1'	System	13 Nov 2020 15:39:08

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (7)**

**Generated On: 10 Jun 2021 07:57:35**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '24/Nov/2020 10:01'	(b) (4) System	24 Nov 2020 15:01:46

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 07:57:35

**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.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Nov 2020 17:42:20
User entered 'I'	(b) (4), (b) (6)	24 Nov 2020 15:01:46



**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'USA-US080-2020-MRNA-1273-P301000002'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Yes (Y)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Yes (Y)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44



**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Thomas'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Campbell'	System	13 Nov 2020 15:38:44

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:35

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered '12401 E. 17th Ave 3rd Floor'	Josie Marshall (b) (4)	13 Nov 2020 17:44:51
	(b) (4)	

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:35

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered 'Aurora'	Josie Marshall (b) (4)	13 Nov 2020 17:44:51
	(b) (4)	

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'CO'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered '80045'	Josie Marshall (b) (4)	13 Nov 2020 17:44:51
	(b) (4)	

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered 'US'	System	13 Nov 2020 15:39:08

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	02 Mar 2021 14:42:07
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
	(b) (4)	
User entered '9'	System	14 Dec 2020 14:18:35
User entered '8'	System	08 Dec 2020 17:54:25
User entered '7'	System	27 Nov 2020 19:56:17
User entered '6'	System	25 Nov 2020 17:42:32
User entered '5'	System	24 Nov 2020 15:01:46
User entered '4'	System	24 Nov 2020 13:44:00
User entered '3'	System	20 Nov 2020 14:52:34
User entered '2'	System	16 Nov 2020 14:26:58
User entered '1'	System	13 Nov 2020 15:39:08



**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (8)**

**Generated On: 10 Jun 2021 07:57:35**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '25/Nov/2020 17:42'	(b) (4) System	25 Nov 2020 17:42:32

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 07:57:35

**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.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	27 Nov 2020 19:56:02
User entered 'I'	(b) (4), (b) (6)	25 Nov 2020 17:42:32

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'USA-US080-2020-MRNA-1273-P301000002'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Yes (Y)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Yes (Y)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44



**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Thomas'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Campbell'	System	13 Nov 2020 15:38:44

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:35

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered '12401 E. 17th Ave 3rd Floor'	Josie Marshall (b) (4)	13 Nov 2020 17:44:51
	(b) (4)	

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:35

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered 'Aurora'	Josie Marshall (b) (4)	13 Nov 2020 17:44:51
	(b) (4)	

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'CO'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered '80045'	Josie Marshall (b) (4)	13 Nov 2020 17:44:51
	(b) (4)	



**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered 'US'	System	13 Nov 2020 15:39:08

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	02 Mar 2021 14:42:07
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
	(b) (4)	
User entered '9'	System	14 Dec 2020 14:18:35
User entered '8'	System	08 Dec 2020 17:54:25
User entered '7'	System	27 Nov 2020 19:56:17
User entered '6'	System	25 Nov 2020 17:42:32
User entered '5'	System	24 Nov 2020 15:01:46
User entered '4'	System	24 Nov 2020 13:44:00
User entered '3'	System	20 Nov 2020 14:52:34
User entered '2'	System	16 Nov 2020 14:26:58
User entered '1'	System	13 Nov 2020 15:39:08

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (9)**

**Generated On: 10 Jun 2021 07:57:35**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '27/Nov/2020 14:56'	(b) (4) System	27 Nov 2020 19:56:17

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form (9)

Generated On: 10 Jun 2021 07:57:35

**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.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	08 Dec 2020 17:51:10
User entered 'I'	(b) (4), (b) (6)	27 Nov 2020 19:56:17

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'USA-US080-2020-MRNA-1273-P301000002'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Yes (Y)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44



**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Yes (Y)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Thomas'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Campbell'	System	13 Nov 2020 15:38:44

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:35

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered '12401 E. 17th Ave 3rd Floor'	Josie Marshall (b) (4)	13 Nov 2020 17:44:51
	(b) (4)	

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered 'Aurora'	Josie Marshall (b) (4)	13 Nov 2020 17:44:51
	(b) (4)	



**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'CO'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered '80045'	Josie Marshall (b) (4) (b) (4)	13 Nov 2020 17:44:51

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered 'US'	System	13 Nov 2020 15:39:08

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	02 Mar 2021 14:42:07
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
	(b) (4)	
User entered '9'	System	14 Dec 2020 14:18:35
User entered '8'	System	08 Dec 2020 17:54:25
User entered '7'	System	27 Nov 2020 19:56:17
User entered '6'	System	25 Nov 2020 17:42:32
User entered '5'	System	24 Nov 2020 15:01:46
User entered '4'	System	24 Nov 2020 13:44:00
User entered '3'	System	20 Nov 2020 14:52:34
User entered '2'	System	16 Nov 2020 14:26:58
User entered '1'	System	13 Nov 2020 15:39:08

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (10)**

**Generated On: 10 Jun 2021 07:57:35**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '14/Dec/2020 06:18'	(b) (4) System	14 Dec 2020 14:18:35

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form (10)

Generated On: 10 Jun 2021 07:57:35

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 14:41:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'I'	(b) (4) (b) (4), (b) (6)	14 Dec 2020 14:18:35

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'USA-US080-2020-MRNA-1273-P301000002'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Yes (Y)'	System	13 Nov 2020 15:38:44



**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Yes (Y)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Thomas'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Campbell'	System	13 Nov 2020 15:38:44



US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:35

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered '12401 E. 17th Ave 3rd Floor'	Josie Marshall (b) (4)	13 Nov 2020 17:44:51
	(b) (4)	

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:35

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered 'Aurora'	Josie Marshall (b) (4)	13 Nov 2020 17:44:51
	(b) (4)	

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'CO'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered '80045'	Josie Marshall (b) (4)	13 Nov 2020 17:44:51
	(b) (4)	

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered 'US'	System	13 Nov 2020 15:39:08

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	02 Mar 2021 14:42:07
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
	(b) (4)	
User entered '9'	System	14 Dec 2020 14:18:35
User entered '8'	System	08 Dec 2020 17:54:25
User entered '7'	System	27 Nov 2020 19:56:17
User entered '6'	System	25 Nov 2020 17:42:32
User entered '5'	System	24 Nov 2020 15:01:46
User entered '4'	System	24 Nov 2020 13:44:00
User entered '3'	System	20 Nov 2020 14:52:34
User entered '2'	System	16 Nov 2020 14:26:58
User entered '1'	System	13 Nov 2020 15:39:08

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (11)**

**Generated On: 10 Jun 2021 07:57:35**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered '08/Dec/2020 12:54'	(b) (4) System	08 Dec 2020 17:54:25

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form (11)

Generated On: 10 Jun 2021 07:57:35

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 14:41:57
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
User entered 'I'	(b) (4) (b) (4), (b) (6)	08 Dec 2020 17:54:25



**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'USA-US080-2020-MRNA-1273-P301000002'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Yes (Y)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Yes (Y)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'No (N)'	System	13 Nov 2020 15:38:44



**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Thomas'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'Campbell'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered '12401 E. 17th Ave 3rd Floor'	Josie Marshall (b) (4) (b) (4)	13 Nov 2020 17:44:51

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:35

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered 'Aurora'	Josie Marshall (b) (4)	13 Nov 2020 17:44:51
	(b) (4)	

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 15:39:01
User entered 'CO'	System	13 Nov 2020 15:38:44

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 14:52:24
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:02:31
Un-reviewed for Safety.	System	16 Nov 2020 14:26:58
User entered empty.	System	16 Nov 2020 14:26:58
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered '80045'	Josie Marshall (b) (4)	13 Nov 2020 17:44:51
	(b) (4)	

**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:57:35**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 22:02:31
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 14:26:44
User entered 'US'	System	13 Nov 2020 15:39:08

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:57:35

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '10'	System	02 Mar 2021 14:42:07
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:50:06
	(b) (4)	
User entered '9'	System	14 Dec 2020 14:18:35
User entered '8'	System	08 Dec 2020 17:54:25
User entered '7'	System	27 Nov 2020 19:56:17
User entered '6'	System	25 Nov 2020 17:42:32
User entered '5'	System	24 Nov 2020 15:01:46
User entered '4'	System	24 Nov 2020 13:44:00
User entered '3'	System	20 Nov 2020 14:52:34
User entered '2'	System	16 Nov 2020 14:26:58
User entered '1'	System	13 Nov 2020 15:39:08



**US3502142**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000002**

**Form: Safety Report Form (12)**

**Generated On: 10 Jun 2021 07:57:35**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User entered '02/Mar/2021 09:42'	(b) (4) System	02 Mar 2021 14:42:07

US3502142

Folder: SAE USA-US080-2020-MRNA-1273-P301000002

Form: Safety Report Form (12)

Generated On: 10 Jun 2021 07:57:35

**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.	Thomas Campbell (b) (4)	19 Mar 2021 19:43:49
User entered 'I'	(b) (4) (b) (4), (b) (6)	02 Mar 2021 14:42:07