

US3502045 (Prod: University of Colorado Hospital)

Generated By: KC Joubran

Generated On: 10 Jun 2021 07:55:38

All time stamps listed in this document are displayed in GMT

US3502045

Form: Participant Creation

Data signed: (b) (4) 16 Feb 2021 15:13:48

Generated On: 10 Jun 2021 07:55:38

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Participant ID

US3502045

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

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US3502045

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

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

Visit date (dd MMM yyyy)	28 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3502045

Folder: Screening

Form: Demographics

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

Date of Birth (MMM yyyy)	(b) (6) 1965
Age	55
Age Units	YEARS
Age (Derived)	55
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 16 Feb 2021 15:13:49

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	28 AUG 2020
Month and Year of Informed Consent (derived)	AUG 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

US3502045

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 16 Feb 2021 15:13:49

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 16 Feb 2021 15:13:49

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

Condition	MIGRAINES
Start date (dd MMM yyyy)	UN UNK 2006
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1970
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 1970
Start Year (derived)	1970
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

Condition	HIGH CHOLESTEROL
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Start Year (derived)	1998
Stop Month and Year (derived)	
Stop Year (derived)	

US3502045

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

Condition	MUSCLE SPASMS - LOW BACK
Start date (dd MMM yyyy)	UN UNK 2020
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 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

Condition	ARTHRITIS (OSTEOARTHRITIS) - BILATERAL HANDS AND FEET
Start date (dd MMM yyyy)	UN APR 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

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

US3502045

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	28 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	08:23 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 08:23
Height ( <i>xxx.x</i> )	162.5 cm
Weight ( <i>xxx.x</i> )	151 lb
BMI ( <i>xxx.x</i> )	25.99247 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 AUG 2020

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



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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 16 Feb 2021 15:13:49

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Date of assessment (dd MMM yyyy) 28 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

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

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 2018

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 16 Feb 2021 15:13:49

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 16 Feb 2021 15:13:49

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

What was the date of randomization? (dd MMM yyyy) 28 AUG 2020

What was the participant's randomization number? 145094

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

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

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

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

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

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

Liver Disease Yes ☐   
 No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐   
 No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

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)	28 AUG 2020
Time of assessment (00:00-23:59)	07:45 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 07:45
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3502045

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

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)	28 AUG 2020
Time of assessment (00:00-23:59)	08:54 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 08:54
Temperature (xxx.x)	36.0 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	FOREHEAD
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG



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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

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.*

US3502045

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 28 AUG 2020

What was the treatment time? (00:00-23:59) 08:22 (24 HR)

Treatment Date and Time (derived) 28 AUG 2020 08:22

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 AUG 2020
Collection time (00:00-23:59)	08:10 (24 HR)
Collection date and time (derived)	28 AUG 2020 08:10

US3502045

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

Collection date (dd MMM yyyy)			28 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:17	28 AUG 2020 08:17
Nasopharyngeal Swab 2	No		

US3502045

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 08:48

PC Open Date & Time

28 AUG 2020 08:42

PC Close Date & Time

28 AUG 2020 11:12

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☐  
No ☐

Please record your **TEMPERATURE** in °F

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time 28 AUG 2020 12:07

PC Close Date & Time 29 AUG 2020 11:59

US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:55:38

**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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 13:07

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59



US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:55:38

**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

97.2 °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

31 AUG 2020 19:52

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:55:38

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 22:21

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

02 SEP 2020 16:32

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 21:32

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

**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

28 AUG 2020 08:48

PC Open Date & Time

28 AUG 2020 08:42

PC Close Date & Time

28 AUG 2020 11:12

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

28 AUG 2020 12:07

PC Close Date & Time

29 AUG 2020 11:59

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:55:38

**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

29 AUG 2020 13:14

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59



US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:55:38

**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

31 AUG 2020 19:52

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 22:22

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:55:38

**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

02 SEP 2020 16:32

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:55:38

**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

03 SEP 2020 21:32

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

**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 ☐

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 08:49
PC Open Date & Time	28 AUG 2020 08:42
PC Close Date & Time	28 AUG 2020 11:12

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

**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 ☐



US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

28 AUG 2020 12:07

PC Close Date & Time

29 AUG 2020 11:59

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:55:38

**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 ☒

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:55:38

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 13:15
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:55:38

Yes ☐

PC Time stamp

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 4

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:55:38

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 19:53
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:55:38

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 22:22
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:55:38

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

57 of 2695

EAB) (1725)

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:55:38

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 16:33
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:55:38

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 ☒

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:55:38

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 21:33
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3502045

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☐

**HEADACHE**

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 ☐

PC Time Stamp

04 SEP 2020 19:55

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3502045

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your

**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 ☐

PC Time Stamp 05 SEP 2020 13:00

PC Open Date & Time 05 SEP 2020 12:00

PC Close Date & Time 06 SEP 2020 11:59

US3502045

Folder: Diary Dose 1 (1)

Form: Headache\_Day(10)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

DAY 10

Select one response below to indicate the intensity of your

None ☒

**HEADACHE**

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 ☐

PC Time Stamp

07 SEP 2020 10:14

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59



US3502045

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(8)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

04 SEP 2020 19:55

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3502045

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

DAY 9

Select one response below to indicate the intensity of your

None ☐

**FATIGUE**

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 05 SEP 2020 13:00

PC Open Date & Time 05 SEP 2020 12:00

PC Close Date & Time 06 SEP 2020 11:59

US3502045

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(10)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

DAY 10

Select one response below to indicate the intensity of your

None ☒

**FATIGUE**

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

PC Time Stamp

07 SEP 2020 10:14

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3502045

Folder: Diary Dose 1 (1)

Form: Nausea\_Day(8)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

DAY 8

Select one response below to indicate the level of your

**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 ☐

PC Time stamp

04 SEP 2020 19:55

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3502045

Folder: Diary Dose 1 (1)

Form: Nausea\_Day(9)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

DAY 9

Select one response below to indicate the level of your

**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 ☐

PC Time stamp 05 SEP 2020 13:00

PC Open Date & Time 05 SEP 2020 12:00

PC Close Date & Time 06 SEP 2020 11:59

US3502045

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 07:55:38

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	04 SEP 2020 19:55
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3502045

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 07:55:38

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	05 SEP 2020 13:01
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3502045

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 07:55:38

<b>TIMEPOINT</b>	DAY 10
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	07 SEP 2020 10:14
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59



US3502045

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3502045

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3502045

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3502045

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3502045

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3502045

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3502045

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 15:13:50

Generated On: 10 Jun 2021 07:55:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3502045

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 15:13:50

Generated On: 10 Jun 2021 07:55:38

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 SEP 2020
Time of assessment (00:00-23:59)	07:25 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 07:25
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	TEMPORAL
Pulse (xxx)	81 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)	71 mmHg
Diastolic Blood Pressure units	MMHG



US3502045

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 15:13:50

Generated On: 10 Jun 2021 07:55:38

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)	25 SEP 2020
Time of assessment (00:00-23:59)	08:33 (24 HR)
Vital Signs Date and Time (derived)	25 SEP 2020 08:33
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)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3502045

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 15:13:50

Generated On: 10 Jun 2021 07:55:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 SEP 2020

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

US3502045

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 15:13:50

Generated On: 10 Jun 2021 07:55:38

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 08:03 (24 HR)

Treatment Date and Time (derived) 25 SEP 2020 08:03

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

US3502045

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 15:13:50

Generated On: 10 Jun 2021 07:55:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 SEP 2020
Collection time (00:00-23:59)	07:47 (24 HR)
Collection date and time (derived)	25 SEP 2020 07:47

US3502045

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 15:13:50

Generated On: 10 Jun 2021 07:55:38

Collection date (dd MMM yyyy)			25 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	07:53	25 SEP 2020 07:53
Nasopharyngeal Swab 2	No		

US3502045

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:13:50

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

25 SEP 2020 08:24

PC Open Date & Time

25 SEP 2020 08:23

PC Close Date & Time

25 SEP 2020 10:53

US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

**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

97.7 °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

25 SEP 2020 16:49

PC Open Date & Time

25 SEP 2020 11:48

PC Close Date & Time

26 SEP 2020 11:59



US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:55:38

**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

98.2 °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

26 SEP 2020 18:46

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:55:38

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.2 °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

27 SEP 2020 17:35

---

PC Open Date & Time

27 SEP 2020 12:00

---

PC Close Date & Time

28 SEP 2020 11:59

---

US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:55:38

**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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 15:47

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:55:38

---

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 19:21

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:55:38

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**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

98.1 °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

30 SEP 2020 16:48

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 21:17

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

**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

25 SEP 2020 08:25

PC Open Date & Time

25 SEP 2020 08:23

PC Close Date & Time

25 SEP 2020 10:53

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 16:50

PC Open Date & Time

25 SEP 2020 11:48

PC Close Date & Time

26 SEP 2020 11:59



US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:55:38

**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

26 SEP 2020 18:47

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:55:38

**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

27 SEP 2020 17:35

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:55:38

**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

28 SEP 2020 15:47

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 19:22

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:55:38

**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

30 SEP 2020 16:49

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:55:38

**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

01 OCT 2020 21:17

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

**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 ☐

US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

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

No ☒

Yes ☐

PC Time stamp	25 SEP 2020 08:25
PC Open Date & Time	25 SEP 2020 08:23
PC Close Date & Time	25 SEP 2020 10:53



US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

**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 ☐

US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

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

No ☒

Yes ☐

PC Time stamp	25 SEP 2020 16:50
PC Open Date & Time	25 SEP 2020 11:48
PC Close Date & Time	26 SEP 2020 11:59

US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:55:38

**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 ☒

US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:55:38

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 18:47
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:55:38

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

108 of 2695

EAB) (1725)

US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:55:38

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 17:36
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:55:38

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 15:48
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59



US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:55:38

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

112 of 2695

EAB) (1725)

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:55:38**

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 19:22
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:55:38

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 ☒

US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:55:38

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 16:49
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:55:38

**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 ☒

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US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:55:38

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 21:18
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3502045

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 21:01:44

Generated On: 10 Jun 2021 07:55:38

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 ATTEMPTED X3

*If Contact Not Made, please provide Comments*

US3502045

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3502045

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3502045

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3502045

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3502045

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3502045

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 15:13:50

Generated On: 10 Jun 2021 07:55:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3502045

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 15:13:50

Generated On: 10 Jun 2021 07:55:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 OCT 2020
Time of assessment (00:00-23:59)	07:22 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 07:22
Temperature (xxx.x)	35.9 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3502045

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 15:13:50

Generated On: 10 Jun 2021 07:55:38

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.*

US3502045

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 15:13:50

Generated On: 10 Jun 2021 07:55:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 OCT 2020
Collection time (00:00-23:59)	07:41 (24 HR)
Collection date and time (derived)	23 OCT 2020 07:41



US3502045

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:13:50

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3502045

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

<b>TIMEPOINT</b>	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 OCT 2020 21:30:01
Patient Cloud Open Date & Time	28 OCT 2020 00:01
Patient Cloud Close Date & Time	01 NOV 2020 23:59

US3502045

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 NOV 2020 20:06:29

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3502045

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	14 NOV 2020 21:02:01
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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	26 NOV 2020 22:36:37
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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	01 DEC 2020 20:50:26
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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

06 DEC 2020 14:37:06

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	13 DEC 2020 21:33:33
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59



US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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

21 DEC 2020 18:53:41

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 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"/>

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	27 DEC 2020 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	31 DEC 2020 23:59
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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 16:20:30

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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

11 JAN 2021 21:34:42

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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

18 JAN 2021 07:45:32

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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

24 JAN 2021 07:35:31

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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

31 JAN 2021 21:17:30

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59



US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	08 FEB 2021 20:47:52
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	14 FEB 2021 09:41:10
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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

22 FEB 2021 21:12:06

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	01 MAR 2021 21:22:39
Patient Cloud Open Date & Time	28 FEB 2021 00:01
Patient Cloud Close Date & Time	04 MAR 2021 23:59

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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

10 MAR 2021 13:51:53

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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

15 MAR 2021 15:54:29

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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

21 MAR 2021 14:45:37

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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

28 MAR 2021 13:45:19

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59



US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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

05 APR 2021 13:35:13

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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

11 APR 2021 17:47:56

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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

20 APR 2021 12:44:33

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 06:43:03

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 20:13:11

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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 ☐

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

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[Patient Cloud Close Date & Time](#)

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13 MAY 2021 23:59

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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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



**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

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[Patient Cloud Close Date & Time](#)

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27 MAY 2021 23:59

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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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"/>



**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

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[Patient Cloud Close Date & Time](#)

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17 JUN 2021 23:59

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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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 ☐

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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"/>



**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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

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

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐



**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°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"/>

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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 ☐

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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"/>

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

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[Patient Cloud Close Date & Time](#)

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16 SEP 2021 23:59

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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

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[Patient Cloud Close Date & Time](#)

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23 SEP 2021 23:59

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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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 ☐

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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"/>



**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

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[Patient Cloud Close Date & Time](#)

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07 OCT 2021 23:59

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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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"/>

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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 ☐

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 OCT 2021 23:59

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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 ☐

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	24 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	28 OCT 2021 23:59
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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

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[Patient Cloud Close Date & Time](#)

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04 NOV 2021 23:59

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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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"/>

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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 ☐

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 NOV 2021 23:59

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°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"/>

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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 ☐

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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"/>

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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"/>



**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	26 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	30 DEC 2021 23:59
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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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 ☐

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

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[Patient Cloud Close Date & Time](#)

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13 JAN 2022 23:59

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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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 ☐

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

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20 JAN 2022 23:59

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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 ☐



**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

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[Patient Cloud Close Date & Time](#)

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27 JAN 2022 23:59

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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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 ☐

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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"/>

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

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[Patient Cloud Close Date & Time](#)

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10 FEB 2022 23:59

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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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 ☐

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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 ☐



**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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 ☐

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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 ☐

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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 ☐



**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 MAR 2022 23:59

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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°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 ☐

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

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[Patient Cloud Open Date & Time](#)

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27 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAR 2022 23:59

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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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 ☐

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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"/>

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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"/>

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

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[Patient Cloud Close Date & Time](#)

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12 MAY 2022 23:59

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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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



**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

22 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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"/>

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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 ☐

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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"/>

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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 ☐

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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"/>



**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

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[Patient Cloud Close Date & Time](#)

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21 JUL 2022 23:59

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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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 ☐

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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°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 ☐



**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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°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 ☐

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

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[Patient Cloud Open Date & Time](#)

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14 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 AUG 2022 23:59

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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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"/>

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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"/>

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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"/>



**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 SEP 2022 23:59

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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 ☐

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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"/>



**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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°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 ☐

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 OCT 2022 23:59

US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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 ☐

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

**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 ☐

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3502045

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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="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"/>



**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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US3502045

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 07:55:38

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
Yes	Yes	01 MAR 2021 21:24:22

US3502045

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3502045

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3502045

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3502045

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3502045

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 21:45:26

Generated On: 10 Jun 2021 07:55:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

PT IN FOR DECISION VISIT

1/26/21

*If Contact Not Made, please provide Comments*

US3502045

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3502045

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 19:39:03

Generated On: 10 Jun 2021 07:55:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3502045

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 19:39:03

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3502045

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 21:01:44

Generated On: 10 Jun 2021 07:55:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3502045

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 21:01:44

Generated On: 10 Jun 2021 07:55:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 MAR 2021
Time of assessment (00:00-23:59)	10:55 (24 HR)
Vital Signs Date and Time (derived)	22 MAR 2021 10:55
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3502045

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 21:01:44

Generated On: 10 Jun 2021 07:55:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 MAR 2021

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

US3502045

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 21:01:44

Generated On: 10 Jun 2021 07:55:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 MAR 2021
Collection time (00:00-23:59)	11:10 (24 HR)
Collection date and time (derived)	22 MAR 2021 11:10

US3502045

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 21:01:44

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3502045

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:39:55

Generated On: 10 Jun 2021 07:55:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3502045

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:39:55

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3502045**

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

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

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*

**US3502045**

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

**Form: Continuing**

**Generated On: 10 Jun 2021 07:55:38**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3502045**

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

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 07:55:38**

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"/>

**US3502045**

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

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

**Generated On: 10 Jun 2021 07:55:38**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3502045

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

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 15:13:48

Generated On: 10 Jun 2021 07:55:38

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

Visit date (dd MMM yyyy)	26 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3502045

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

Form: Unblinding

Data signed: (b) (4) 19 Mar 2021 19:39:03

Generated On: 10 Jun 2021 07:55:38

Date of updated informed consent ( <i>dd MMM yyyy</i> )	26 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> )	26 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

US3502045

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Feb 2021 15:13:48

Generated On: 10 Jun 2021 07:55:38

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



US3502045

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 15:13:48

Generated On: 10 Jun 2021 07:55:38

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)	26 JAN 2021
Time of assessment (00:00-23:59)	15:46 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 15:46
Temperature (xxx.x)	35.5 C
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)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

US3502045

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 15:13:48

Generated On: 10 Jun 2021 07:55:38

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 checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 JAN 2021
Time of assessment (00:00-23:59)	16:44 (24 HR)
Vital Signs Date and Time (derived)	26 JAN 2021 16:44
Temperature (xxx.x)	98 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3502045

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

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 15:13:48

Generated On: 10 Jun 2021 07:55:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 JAN 2021

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

US3502045

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

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 15:13:48

Generated On: 10 Jun 2021 07:55:38

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) 26 JAN 2021

What was the treatment time? (00:00-23:59) 16:14 (24 HR)

Treatment Date and Time (derived) 26 JAN 2021 16:14

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

What was the frequency of the study treatment dosing? ONCE

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

US3502045

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 15:13:48

Generated On: 10 Jun 2021 07:55:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 JAN 2021

Collection time (00:00-23:59)

16:00 (24 HR)

Collection date and time (derived)

26 JAN 2021 16:00

US3502045

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Feb 2021 15:13:48

Generated On: 10 Jun 2021 07:55:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	26 JAN 2021
Collection time (00:00 - 23:59)	16:01
Collection Date and Time (derived)	26 JAN 2021 16:01

US3502045

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

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 15:13:48

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3502045

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 19:39:03

Generated On: 10 Jun 2021 07:55:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3502045

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 19:39:03

Generated On: 10 Jun 2021 07:55:38

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

US3502045

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Mar 2021 19:39:03

Generated On: 10 Jun 2021 07:55:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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

US3502045

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Mar 2021 19:39:03

Generated On: 10 Jun 2021 07:55:38

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)	24 FEB 2021
Time of assessment (00:00-23:59)	15:28 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 15:28
Temperature (xxx.x)	36.3 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	63 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)	59 mmHg
Diastolic Blood Pressure units	MMHG

US3502045

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Mar 2021 19:39:03

Generated On: 10 Jun 2021 07:55:38

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)	24 FEB 2021
Time of assessment (00:00-23:59)	16:07 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 16:07
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3502045

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Mar 2021 19:39:03

Generated On: 10 Jun 2021 07:55:38

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

24 FEB 2021

---

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

---

US3502045

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 19 Mar 2021 19:39:03

Generated On: 10 Jun 2021 07:55:38

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) 24 FEB 2021

What was the treatment time? (00:00-23:59) 15:37 (24 HR)

Treatment Date and Time (derived) 24 FEB 2021 15:37

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

US3502045

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 19:39:03

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3502045

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Mar 2021 19:39:03

Generated On: 10 Jun 2021 07:55:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3502045

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 19 Mar 2021 19:39:03

Generated On: 10 Jun 2021 07:55:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3502045

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 21:01:44

Generated On: 10 Jun 2021 07:55:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 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

US3502045

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 21:01:44

Generated On: 10 Jun 2021 07:55:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	22 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	10:55 (24 HR)
Vital Signs Date and Time (derived)	22 MAR 2021 10:55
Temperature ( <i>xxx.x</i> )	36.6 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> )	61 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	60 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3502045

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 21:01:44

Generated On: 10 Jun 2021 07:55:38

---

Was the physical examination performed?

Yes ☒

No ☐

---

Date of examination (dd MMM yyyy)

22 MAR 2021

---

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

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US3502045

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 21:01:44

Generated On: 10 Jun 2021 07:55:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 MAR 2021
Collection time (00:00-23:59)	11:10 (24 HR)
Collection date and time (derived)	22 MAR 2021 11:10

US3502045

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Feb 2021 15:13:48

Generated On: 10 Jun 2021 07:55:38

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3502045

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 10:46:51

Generated On: 10 Jun 2021 07:55:38

AEID	USA-US080-2020-MRNA-1273-P30 1000001
Adverse event	MIGRAINE EXACERBATION
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)	16 SEP 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 SEP 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 checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	22 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	23 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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US3502045

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 10:46:51

Generated On: 10 Jun 2021 07:55:38

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	



US3502045

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 10:46:51

Generated On: 10 Jun 2021 07:55:38

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PT SUFFERS FROM MIGRAINES AND IS DOCUMENTED IN HISTORY PRIOR TO ENROLLING INTO TRIAL. SHE RECEIVED HER FIRST DOSE ON 04SEP2020. PT PRESENTED TO LOCAL ED ON 16SEP2020 FOR COMPLAINT OF ACUTE MIGRAINE. SHE WAS TREATED IN ED AND DISCHARGED HOME. PT RETURNED TO ED ON 22SEP2020 WITH COMPLAINT OF MIGRAINE PAIN THAT WARRANTED HIGHER LEVEL OF CARE. PT KEPT OVERNIGHT FOR OBSERVATION AND HAD MRI COMPLETED. MRI OF BRAIN WITH AND WITHOUT CONTRAST WAS UNREMARKABLE AND PT DISCHARGED ON 23SEP2020 AFTER NOTING IMPROVEMENT IN SYMPTOMS. SHE WAS DIRECTED TO FOLLOW-UP WITH HER NEUROLOGIST WHO HAD CONSULTED WITH ED STAFF AND FLOOR HOSPITALIST TO GUIDE TREATMENT PLAN. PT REPORTS THAT SHE DOES NOT HAVE KNOWN TRIGGERS FOR EXACERBATION OF MIGRAINE HISTORY. SHE REPORTS THAT OFTEN TIMES SHE CAN SIMPLY "WAKE-UP" WITH A MIGRAINE OR NOT HAVE ANY WARNING WHATSOEVER. SHE DOES NOT EXPERIENCE AURAS, AND IS UNABLE TO IDENTIFY ANY KNOWN RISK FACTORS INCLUDING DIET, STRESS, CHANGES IN WEATHER OR FATIGUE.

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**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Data signed:** (b) (4) 28 Apr 2021 10:46:51

**Generated On: 10 Jun 2021 07:55:38**

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

US3502045

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 10:46:51

Generated On: 10 Jun 2021 07:55:38

AEID

Adverse event

MILK ALLERGY DIAGNOSIS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

12 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

21 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 10:46:51

Generated On: 10 Jun 2021 07:55:38

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input 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:	CONTINUED DIET MODIFICATION
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3502045

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 10:46:51

Generated On: 10 Jun 2021 07:55:38

AEID	
Adverse event	SEASONAL ALLERGY EXACERBATION
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)	15 OCT 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 checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 10:46:51

Generated On: 10 Jun 2021 07:55:38

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3502045

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 10:46:51

Generated On: 10 Jun 2021 07:55:38

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input 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)	02 SEP 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)	06 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 10:46:51

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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 type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
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)	



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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 10:46:51

Generated On: 10 Jun 2021 07:55:38

AEID	
Adverse event	NAUSEA
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input 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)	01 SEP 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)	05 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 10:46:51

Generated On: 10 Jun 2021 07:55:38

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 16 Feb 2021 15:13:48

Generated On: 10 Jun 2021 07:55:38

---

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

Yes ☒

No ☐

---

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

---

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Mar 2021 19:39:02

Generated On: 10 Jun 2021 07:55:38

Name of Medication TROKENDI

Prophylaxis Yes ☒  
No ☐

Indication MIGRAINE 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 ☐

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US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Mar 2021 19:39:02

Generated On: 10 Jun 2021 07:55:38

	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 2007	
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)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Mar 2021 19:39:02

Generated On: 10 Jun 2021 07:55:38

Name of Medication NALTREXONE

Prophylaxis Yes ☒  
No ☐

Indication MIGRAINE PREVENTION

Dose per administration 4.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Mar 2021 19:39:02

Generated On: 10 Jun 2021 07:55:38

	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 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Mar 2021 19:39:02

Generated On: 10 Jun 2021 07:55:38

Name of Medication SERTRALINE

Prophylaxis Yes ☒  
No ☐

Indication MIGRAINE 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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Mar 2021 19:39:02

Generated On: 10 Jun 2021 07:55:38

	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 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Mar 2021 19:39:02

Generated On: 10 Jun 2021 07:55:38

Name of Medication ROSUVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HIGH CHOLESTEROL

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Mar 2021 19:39:02

Generated On: 10 Jun 2021 07:55:38

	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 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Mar 2021 19:39:02

Generated On: 10 Jun 2021 07:55:38

Name of Medication MAGNESIUM

Prophylaxis Yes ☒  
No ☐

Indication GENERAL WELLNESS

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Mar 2021 19:39:02

Generated On: 10 Jun 2021 07:55:38

	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 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Mar 2021 19:39:02

Generated On: 10 Jun 2021 07:55:38

Name of Medication COQ10

Prophylaxis Yes ☒  
No ☐

Indication GENERAL WELLNESS

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Mar 2021 19:39:02

Generated On: 10 Jun 2021 07:55:38

	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 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 19 Mar 2021 19:39:02

Generated On: 10 Jun 2021 07:55:38

Name of Medication ZYRTEC

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 19 Mar 2021 19:39:02

Generated On: 10 Jun 2021 07:55:38

	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 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 19 Mar 2021 19:39:02

Generated On: 10 Jun 2021 07:55:38

Name of Medication REYVOW

Prophylaxis Yes ☒  
No ☐

Indication MIGRAINE 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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 19 Mar 2021 19:39:02

Generated On: 10 Jun 2021 07:55:38

	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 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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 19 Mar 2021 19:39:02

Generated On: 10 Jun 2021 07:55:38

Name of Medication PROMETHAZINE

Prophylaxis Yes ☒  
No ☐

Indication MIGRAINE RELATED NAUSEA  
PREVENTION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 19 Mar 2021 19:39:02

Generated On: 10 Jun 2021 07:55:38

	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)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 19 Mar 2021 19:39:02

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Name of Medication FLOVENT

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

Dose per administration 110

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 19 Mar 2021 19:39:02

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 19 Mar 2021 19:39:02

Generated On: 10 Jun 2021 07:55:38

Name of Medication ALBUTEROL

Prophylaxis Yes ☐  
No ☒

Indication ASTHMA

Dose per administration 90

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 19 Mar 2021 19:39:02

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 19 Mar 2021 19:39:02

Generated On: 10 Jun 2021 07:55:38

Name of Medication BIOTIN

Prophylaxis Yes ☐  
No ☒

Indication GENERAL WELLNESS

Dose per administration 5000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 19 Mar 2021 19:39:02

Generated On: 10 Jun 2021 07:55:38

	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 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 19 Mar 2021 19:39:02

Generated On: 10 Jun 2021 07:55:38

Name of Medication VALPROATE

Prophylaxis Yes ☐  
No ☒

Indication TREATMENT OF ACUTE  
MIGRAINE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 19 Mar 2021 19:39:02

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input 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)		16 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 19 Mar 2021 19:39:02

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Name of Medication PROMETHAZINE

Prophylaxis Yes ☐  
No ☒

Indication TREATMENT OF ACUTE  
MIGRAINE

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 19 Mar 2021 19:39:02

Generated On: 10 Jun 2021 07:55:38

	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)	16 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 19 Mar 2021 19:39:02

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Name of Medication PROCHLORPERAZINE

Prophylaxis Yes ☐  
No ☒

Indication TREATMENT OF ACUTE  
MIGRAINE

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 19 Mar 2021 19:39:02

Generated On: 10 Jun 2021 07:55:38

	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 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)		16 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 19 Mar 2021 19:39:02

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Name of Medication NORMAL SALINE IVF

Prophylaxis Yes ☐  
No ☒

Indication TREATMENT OF ACUTE  
MIGRAINE

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 19 Mar 2021 19:39:02

Generated On: 10 Jun 2021 07:55:38

	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 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)		16 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 19 Mar 2021 19:39:02

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Name of Medication MAGNISIIUM SULFATE

Prophylaxis Yes ☐  
No ☒

Indication TREATMENT OF ACUTE  
MIGRAINE

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 19 Mar 2021 19:39:02

Generated On: 10 Jun 2021 07:55:38

	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 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)		16 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 19 Mar 2021 19:39:02

Generated On: 10 Jun 2021 07:55:38

Name of Medication DIPHENHYDRAMINE

Prophylaxis Yes ☐  
No ☒

Indication TREATMENT OF ACUTE  
MIGRAINE

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 19 Mar 2021 19:39:02

Generated On: 10 Jun 2021 07:55:38

	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 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)		16 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 19 Mar 2021 19:39:02

Generated On: 10 Jun 2021 07:55:38

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐  
No ☒

Indication TREATMENT OF ACUTE  
MIGRAINE

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 19 Mar 2021 19:39:02

Generated On: 10 Jun 2021 07:55:38

	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 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)		16 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 19 Mar 2021 19:39:02

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Name of Medication COMPAZINE

Prophylaxis Yes ☐  
No ☒

Indication TREATMENT OF MIGRAINE

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 19 Mar 2021 19:39:02

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 19 Mar 2021 19:39:02

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Name of Medication BENADRYL

Prophylaxis Yes ☐  
No ☒

Indication TREATMENT OF MIGRAINE

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 19 Mar 2021 19:39:02

Generated On: 10 Jun 2021 07:55:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 19 Mar 2021 19:39:02

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Name of Medication MAGNESIUM SULFATE

Prophylaxis Yes ☐  
No ☒

Indication TREATMENT OF MIGRAINE

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 19 Mar 2021 19:39:02

Generated On: 10 Jun 2021 07:55:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 19 Mar 2021 19:39:02

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Name of Medication NORMAL SALINE IVF

Prophylaxis Yes ☐  
No ☒

Indication TREATMENT OF MIGRAINE

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 19 Mar 2021 19:39:02

Generated On: 10 Jun 2021 07:55:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

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Name of Medication LORAZEPAM

Prophylaxis Yes ☐  
No ☒

Indication TREATMENT OF MIGRAINE

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 19 Mar 2021 19:39:02

Generated On: 10 Jun 2021 07:55:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		22 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 19 Mar 2021 19:39:02

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Name of Medication TORADOL

Prophylaxis Yes ☐  
No ☒

Indication TREATMENT OF MIGRAINE

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 19 Mar 2021 19:39:02

Generated On: 10 Jun 2021 07:55:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 23 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

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Generated On: 10 Jun 2021 07:55:38

Name of Medication CYCLOBENZAPRINE

Prophylaxis Yes ☐  
No ☒

Indication MUSCLE SPASMS - LOW BACK

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 19 Mar 2021 19:39:02

Generated On: 10 Jun 2021 07:55:38

	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 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 23 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 19 Mar 2021 19:39:02

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Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication TREATMENT OF MIGRAINE

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 19 Mar 2021 19:39:02

Generated On: 10 Jun 2021 07:55:38

	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)		22 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 23 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 19 Mar 2021 19:39:02

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Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication FLU PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 19 Mar 2021 19:39:02

Generated On: 10 Jun 2021 07:55:38

	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)		12 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)		12 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 19 Mar 2021 19:39:02

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Name of Medication KETOTIFEN

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGY  
EXACERBATION

Dose per administration 1

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

If dose unit is Other, specify GTT

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

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	Intraocular	<input checked="" type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 OCT 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"/>

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Data signed: (b) (4) 19 Mar 2021 19:39:02

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Name of Medication FLONASE

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGY  
EXACERBATION

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 19 Mar 2021 19:39:02

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

US3502045

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Feb 2021 15:13:48

Generated On: 10 Jun 2021 07:55:38

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---



US3502045

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 16 Feb 2021 15:13:48

Generated On: 10 Jun 2021 07:55:38

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
22 SEP 2020	MRI OF BRAIN	Adverse Event	

US3502045

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 07:55:38

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

US3502045

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 07:55:38

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 ☐

US3502045

Folder: SAE USA-US080-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

SAEID	USA-US080-2020-MRNA-1273-P301000001
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	12401 E. 17TH AVE 3RD FLOOR
Site Address: City	AURORA
Site Address: State	CO
Site Address: Postal Code	80045
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3502045

Folder: SAE USA-US080-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

SAEID	USA-US080-2020-MRNA-1273-P301000001
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	12401 E. 17TH AVE 3RD FLOOR
Site Address: City	AURORA
Site Address: State	CO
Site Address: Postal Code	80045
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	25/SEP/2020 14:55
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3502045

Folder: SAE USA-US080-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 16 Feb 2021 15:13:49

Generated On: 10 Jun 2021 07:55:38

SAEID	USA-US080-2020-MRNA-1273-P301000001
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	12401 E. 17TH AVE 3RD FLOOR
Site Address: City	AURORA
Site Address: State	CO
Site Address: Postal Code	80045
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	26/OCT/2020 14:16
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

US3502045 (Prod: University of Colorado Hospital)

**US3502045**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 07:55:38**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'US3502045'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 13:29:26



**US3502045**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:55:38**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	(b) (4) Amy Harrison (b) (4)	28 Aug 2020 13:38:46

US3502045

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '28 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 13:29:27

US3502045

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Clinic (Clinic)'	Amy Harrison (b) (4)	28 Aug 2020 13:38:46

**US3502045**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:55:38**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered 'SCRN'	System	28 Aug 2020 13:38:46

**US3502045**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:55:38**

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered (b) (6) 1965'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 13:29:28

US3502045

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:55:38

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '55'	(b) (4) Amy Harrison (b) (4)	28 Aug 2020 13:39:05

**US3502045**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:55:38**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered 'YEARS'	System	28 Aug 2020 13:39:05

**US3502045**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:55:38**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered '55'	System	28 Aug 2020 13:39:43



US3502045

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:55:38

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Female (F)'	(b) (4) Amy Harrison (b) (4)	28 Aug 2020 13:39:05

US3502045

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:55:38

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4) Amy Harrison (b) (4)	28 Aug 2020 13:39:05

**US3502045**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:55:38**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'I'	(b) (4) Amy Harrison (b) (4)	28 Aug 2020 13:39:05

**US3502045**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:55:38**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '0'	(b) (4) Amy Harrison (b) (4)	28 Aug 2020 13:39:05

**US3502045**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:55:38**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '0'	(b) (4) Amy Harrison (b) (4)	28 Aug 2020 13:39:05

**US3502045**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:55:38**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '0'	(b) (4) Amy Harrison (b) (4)	28 Aug 2020 13:39:05

**US3502045**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:55:38**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '0'	(b) (4) Amy Harrison (b) (4)	28 Aug 2020 13:39:05

**US3502045**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:55:38**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '0'	(b) (4) Amy Harrison (b) (4)	28 Aug 2020 13:39:05



US3502045

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:55:38

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered empty.	(b) (4) Amy Harrison (b) (4)	28 Aug 2020 13:39:05

**US3502045**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:55:38**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '0'	(b) (4) Amy Harrison (b) (4)	28 Aug 2020 13:39:05

**US3502045**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:55:38**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '0'	(b) (4) Amy Harrison (b) (4)	28 Aug 2020 13:39:05

US3502045

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:55:38

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '28 Aug 2020'	(b) (4) Amy Harrison (b) (4)	28 Aug 2020 13:39:43

**US3502045**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered 'Aug 2020'	System	28 Aug 2020 13:39:43

**US3502045**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered '2020'	System	28 Aug 2020 13:39:43

**US3502045**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:55:38**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Amendment 3 (3)'	Amy Harrison (b) (4)	28 Aug 2020 13:39:43

**US3502045**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Amy Harrison (b) (4)	28 Aug 2020 13:39:43



**US3502045**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:55:38**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered empty.	(b) (4) Amy Harrison (b) (4)	28 Aug 2020 13:39:43

US3502045

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:55:38

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered empty.	(b) (4) Amy Harrison (b) (4)	28 Aug 2020 13:39:43

US3502045

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:55:38

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'No (N)'	(b) (4) Amy Harrison (b) (4)	28 Aug 2020 13:39:43

**US3502045**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:55:38**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 13:29:27

**US3502045**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:55:38**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered 'I'	System	28 Aug 2020 13:40:08

US3502045

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Amy Harrison (b) (4)	28 Aug 2020 13:40:08

US3502045

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 07:55:38

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Josie Marshall (b) (4)	31 Aug 2020 19:46:05

US3502045

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:55:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 19:48:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 19:48:10
Data point term sent to Coder	System	31 Aug 2020 19:47:12
User entered 'migraines'	Josie Marshall (b) (4)	31 Aug 2020 19:46:21



**US3502045**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'un UNK 2006'	Josie Marshall (b) (4)	31 Aug 2020 19:46:21

**US3502045**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '0'	Josie Marshall (b) (4)	31 Aug 2020 19:46:21

**US3502045**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Josie Marshall (b) (4)	31 Aug 2020 19:46:21

**US3502045**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered empty.	Josie Marshall (b) (4)	31 Aug 2020 19:46:21

**US3502045**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '0'	Josie Marshall (b) (4)	31 Aug 2020 19:46:21

**US3502045**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered 'Jan 2006'	System	31 Aug 2020 19:46:21

**US3502045**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered '2006'	System	31 Aug 2020 19:46:21

**US3502045**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered empty.	System	31 Aug 2020 19:46:21



**US3502045**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered empty.	System	31 Aug 2020 19:46:21

US3502045

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:55:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 19:47:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 19:47:43
Data point term sent to Coder	System	31 Aug 2020 19:47:12
User entered 'seasonal allergies'	Josie Marshall (b) (4)	31 Aug 2020 19:46:40

**US3502045**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'un UNK 1970'	Josie Marshall (b) (4)	31 Aug 2020 19:46:40

**US3502045**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '0'	Josie Marshall (b) (4)	31 Aug 2020 19:46:40

**US3502045**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Josie Marshall (b) (4)	31 Aug 2020 19:46:40

**US3502045**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 07:55:38**

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered empty.	Josie Marshall (b) (4)	31 Aug 2020 19:46:40

**US3502045**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '0'	Josie Marshall (b) (4)	31 Aug 2020 19:46:40

**US3502045**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered 'Jan 1970'	System	31 Aug 2020 19:46:40



**US3502045**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered '1970'	System	31 Aug 2020 19:46:40

**US3502045**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered empty.	System	31 Aug 2020 19:46:40

**US3502045**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered empty.	System	31 Aug 2020 19:46:40

US3502045

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:55:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User coded data point as SOC: Investigations, HLGTT: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 19:47:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 19:47:43
Data point term sent to Coder	System	31 Aug 2020 19:47:13
User entered 'high cholesterol'	Josie Marshall (b) (4)	31 Aug 2020 19:46:57

**US3502045**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'un UNK 1998'	Josie Marshall (b) (4)	31 Aug 2020 19:46:57

**US3502045**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '0'	Josie Marshall (b) (4)	31 Aug 2020 19:46:57

**US3502045**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 07:55:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Josie Marshall (b) (4)	31 Aug 2020 19:46:57

**US3502045**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered empty.	Josie Marshall (b) (4)	31 Aug 2020 19:46:57



**US3502045**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 07:55:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '0'	Josie Marshall (b) (4)	31 Aug 2020 19:46:57

**US3502045**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered 'Jan 1998'	System	31 Aug 2020 19:46:57

**US3502045**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered '1998'	System	31 Aug 2020 19:46:57

**US3502045**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered empty.	System	31 Aug 2020 19:46:57

**US3502045**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered empty.	System	31 Aug 2020 19:46:57

US3502045

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:55:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 19:47:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 19:47:43
Data point term sent to Coder	System	31 Aug 2020 19:47:13
User entered 'asthma'	Josie Marshall (b) (4)	31 Aug 2020 19:47:12

**US3502045**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'un UNK 2010'	Josie Marshall (b) (4)	31 Aug 2020 19:47:12

**US3502045**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '0'	Josie Marshall (b) (4)	31 Aug 2020 19:47:12



**US3502045**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 07:55:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Josie Marshall (b) (4)	31 Aug 2020 19:47:12

**US3502045**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered empty.	Josie Marshall (b) (4)	31 Aug 2020 19:47:12

**US3502045**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 07:55:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '0'	Josie Marshall (b) (4)	31 Aug 2020 19:47:12

**US3502045**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered 'Jan 2010'	System	31 Aug 2020 19:47:12

**US3502045**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered '2010'	System	31 Aug 2020 19:47:12

**US3502045**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered empty.	System	31 Aug 2020 19:47:12

**US3502045**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered empty.	System	31 Aug 2020 19:47:12

US3502045

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:55:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User closed query 'Per DM CLR: Please specify the location of MUSCLE SPASMS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 05:40:30
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Back muscle spasms - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:20:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:20:22
Data point term sent to Coder	System	03 Nov 2020 17:00:15
Query 'Per DM CLR: Please specify the location of MUSCLE SPASMS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'done' (Site from DM).	Josie Marshall (b) (4) (b) (4)	03 Nov 2020 16:59:59
Coding entries removed.	Josie Marshall (b) (4) (b) (4)	03 Nov 2020 16:59:51
User entered 'MUSCLE SPASMS - low back' reason for change: Data Entry Error	Josie Marshall (b) (4) (b) (4)	03 Nov 2020 16:59:51
User opened query 'Per DM CLR: Please specify the location of MUSCLE SPASMS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 06:57:36
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Muscle spasms - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 16:12:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 16:12:55
Data point term sent to Coder	System	24 Sep 2020 16:11:33



**US3502045**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Condition](#)

Audit	User	Time (GMT)
User entered 'muscle spasms'	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:11:14

**US3502045**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'un UNK 2020'	Josie Marshall (b) (4)	24 Sep 2020 16:11:14

**US3502045**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '0'	Josie Marshall (b) (4)	24 Sep 2020 16:11:14

**US3502045**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Josie Marshall (b) (4)	24 Sep 2020 16:11:14

**US3502045**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered empty.	Josie Marshall (b) (4)	24 Sep 2020 16:11:14

**US3502045**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '0'	Josie Marshall (b) (4)	24 Sep 2020 16:11:14

**US3502045**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered 'Jan 2020'	System	24 Sep 2020 16:11:14

**US3502045**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered '2020'	System	24 Sep 2020 16:11:14



**US3502045**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered empty.	System	24 Sep 2020 16:11:14

**US3502045**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered empty.	System	24 Sep 2020 16:11:14

US3502045

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:55:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4)	06 Nov 2020 04:58:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	06 Nov 2020 04:58:28
User closed query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 05:57:26
Data point term sent to Coder	System	03 Nov 2020 17:00:15
Coding entries removed.	Josie Marshall (b) (4)	03 Nov 2020 16:59:37
User entered 'ARTHRITIS (OSTEOARTHRITIS) - bilateral hands and feet' reason for change: Data Entry Error	Josie Marshall (b) (4)	03 Nov 2020 16:59:37
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4)	03 Nov 2020 16:54:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	03 Nov 2020 16:54:22
Data point term sent to Coder	System	03 Nov 2020 16:54:03
Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'done' (Site from DM).	Josie Marshall (b) (4)	03 Nov 2020 16:54:03
User entered 'ARTHRITIS (OSTEOArthritis)' reason for change: Data Entry Error	Josie Marshall (b) (4)	03 Nov 2020 16:53:53
Coding entries removed.	Josie Marshall (b) (4)	03 Nov 2020 16:53:41

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Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:55:38

Condition

Audit	User	Time (GMT)
User entered 'ARTHRITIS (osteo)' reason for change: Data Entry Error	Josie Marshall (b) (4)	03 Nov 2020 16:53:41
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 10:07:36
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Arthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:53:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:53:23
Data point term sent to Coder	System	16 Oct 2020 22:15:22
User entered 'Arthritis'	Laurel Ware (b) (4) (b) (4)	16 Oct 2020 22:14:30

**US3502045**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'un Apr 2018'	Laurel Ware (b) (4)	16 Oct 2020 22:14:30

**US3502045**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '0'	Laurel Ware (b) (4)	16 Oct 2020 22:14:30

**US3502045**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 07:55:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Laurel Ware (b) (4)	16 Oct 2020 22:14:30

**US3502045**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 07:55:38**

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered empty.	Laurel Ware (b) (4)	16 Oct 2020 22:14:30



**US3502045**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 07:55:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '0'	Laurel Ware (b) (4)	16 Oct 2020 22:14:30

**US3502045**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered 'Apr 2018'	System	16 Oct 2020 22:14:30

**US3502045**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered '2018'	System	16 Oct 2020 22:14:30

**US3502045**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered empty.	System	16 Oct 2020 22:14:30

**US3502045**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered empty.	System	16 Oct 2020 22:14:30

US3502045

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:55:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 17:24:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 17:24:41
Data point term sent to Coder	System	23 Oct 2020 17:23:10
User entered 'post-menopausal'	Josie Marshall (b) (4)	23 Oct 2020 17:22:25

**US3502045**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'un UNK 2018'	Josie Marshall (b) (4)	23 Oct 2020 17:22:25

**US3502045**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '0'	Josie Marshall (b) (4)	23 Oct 2020 17:22:25



**US3502045**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 07:55:38**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Josie Marshall (b) (4)	23 Oct 2020 17:22:25

**US3502045**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 07:55:38**

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered empty.	Josie Marshall (b) (4)	23 Oct 2020 17:22:25

**US3502045**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 07:55:38**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '0'	Josie Marshall (b) (4)	23 Oct 2020 17:22:25

**US3502045**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered 'Jan 2018'	System	23 Oct 2020 17:22:25

**US3502045**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered '2018'	System	23 Oct 2020 17:22:25

**US3502045**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered empty.	System	23 Oct 2020 17:22:25

**US3502045**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered empty.	System	23 Oct 2020 17:22:25

US3502045

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Josie Marshall (b) (4)	31 Aug 2020 19:47:51



**US3502045**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '28 Aug 2020'	Josie Marshall (b) (4)	31 Aug 2020 19:47:51

**US3502045**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '08:23'	Josie Marshall (b) (4)	31 Aug 2020 19:47:51

**US3502045**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered '28 Aug 2020 08:23'	System	31 Aug 2020 19:47:51

**US3502045**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '162.5' cm	Josie Marshall (b) (4)	31 Aug 2020 19:47:51
DataPoint set to visible.	System	28 Aug 2020 13:40:08

**US3502045**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '151' lb	Josie Marshall (b) (4)	31 Aug 2020 19:47:51
DataPoint set to visible.	System	28 Aug 2020 13:40:08

**US3502045**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered '25.99247'	System	31 Aug 2020 19:47:51
DataPoint set to visible.	System	28 Aug 2020 13:40:08

**US3502045**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered 'kg/m2'	System	31 Aug 2020 19:47:51
DataPoint set to visible.	System	28 Aug 2020 13:40:08

US3502045

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered missing code ND - Not Done.	Josie Marshall (b) (4)	31 Aug 2020 19:47:51



US3502045

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered empty.	Josie Marshall (b) (4)	31 Aug 2020 19:47:51

US3502045

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered empty.	Josie Marshall (b) (4)	31 Aug 2020 19:47:51

**US3502045**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered missing code ND - Not Done.	Josie Marshall (b) (4)	31 Aug 2020 19:47:51

**US3502045**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered 'bpm'	System	31 Aug 2020 19:47:51

US3502045

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered missing code ND - Not Done.	Josie Marshall (b) (4)	31 Aug 2020 19:47:51

**US3502045**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered 'breaths/min'	System	31 Aug 2020 19:47:51

US3502045

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered missing code ND - Not Done.	Josie Marshall (b) (4)	31 Aug 2020 19:47:51

**US3502045**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered 'mmHg'	System	31 Aug 2020 19:47:51



US3502045

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered missing code ND - Not Done.	Josie Marshall (b) (4)	31 Aug 2020 19:47:51

**US3502045**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User entered 'mmHg'	System	31 Aug 2020 19:47:51

**US3502045**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08

US3502045

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08

**US3502045**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:55:38**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Josie Marshall (b) (4)	31 Aug 2020 19:48:07

**US3502045**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:55:38**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '28 Aug 2020'	Josie Marshall (b) (4)	31 Aug 2020 19:48:07

**US3502045**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 07:55:38**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '28 Aug 2020'	Josie Marshall (b) (4)	31 Aug 2020 19:48:27

US3502045

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'No (N)'	Josie Marshall (b) (4)	31 Aug 2020 19:48:27



US3502045

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:55:38

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 05:14:07
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'done' (Site from DM).	Josie Marshall (b) (4) (b) (4)	23 Oct 2020 17:22:36
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 02:09:47
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:48:27

**US3502045**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 07:55:38**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered empty.	Josie Marshall (b) (4)	31 Aug 2020 19:48:27

US3502045

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered empty.	Josie Marshall (b) (4)	31 Aug 2020 19:48:27

**US3502045**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 07:55:38**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '0'	Josie Marshall (b) (4)	31 Aug 2020 19:48:27

US3502045

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'un UNK 2018'	Josie Marshall (b) (4)	31 Aug 2020 19:48:27

**US3502045**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 07:55:38**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '0'	Josie Marshall (b) (4)	31 Aug 2020 19:48:27

US3502045

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'No (N)'	Josie Marshall (b) (4)	31 Aug 2020 19:48:51

US3502045

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'No (N)'	Josie Marshall (b) (4)	31 Aug 2020 19:48:51



US3502045

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'No (N)'	Josie Marshall (b) (4)	31 Aug 2020 19:48:51

US3502045

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'No (N)'	Josie Marshall (b) (4)	31 Aug 2020 19:48:51

US3502045

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'No (N)'	Josie Marshall (b) (4)	31 Aug 2020 19:48:51

US3502045

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'No (N)'	Josie Marshall (b) (4)	31 Aug 2020 19:48:51

US3502045

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'No (N)'	Josie Marshall (b) (4)	31 Aug 2020 19:48:51

US3502045

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'No (N)'	Josie Marshall (b) (4)	31 Aug 2020 19:48:51

US3502045

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'No (N)'	Josie Marshall (b) (4)	31 Aug 2020 19:48:51

US3502045

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'No (N)'	Josie Marshall (b) (4)	31 Aug 2020 19:48:51



US3502045

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'No (N)'	Josie Marshall (b) (4)	31 Aug 2020 19:48:51

**US3502045**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 07:55:38**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'No (N)'	Josie Marshall (b) (4)	31 Aug 2020 19:48:51

US3502045

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered empty.	Josie Marshall (b) (4)	31 Aug 2020 19:48:51

US3502045

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '0'	Josie Marshall (b) (4)	31 Aug 2020 19:48:51

US3502045

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '0'	Josie Marshall (b) (4)	31 Aug 2020 19:48:51

US3502045

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Form: Risk of Exposure

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**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '0'	Josie Marshall (b) (4)	31 Aug 2020 19:48:51

US3502045

Folder: Screening

Form: Risk of Exposure

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[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '0'	Josie Marshall (b) (4)	31 Aug 2020 19:48:51

US3502045

Folder: Screening

Form: Risk of Exposure

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Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '0'	Josie Marshall (b) (4)	31 Aug 2020 19:48:51



US3502045

Folder: Screening

Form: Risk of Exposure

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[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'I'	Josie Marshall (b) (4)	31 Aug 2020 19:48:51

US3502045

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '0'	Josie Marshall (b) (4)	31 Aug 2020 19:48:51

US3502045

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:55:38

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 07:57:08
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered empty.	Josie Marshall (b) (4)	31 Aug 2020 19:48:51

**US3502045**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:55:38**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Amy Harrison (b) (4)	28 Aug 2020 13:40:29

US3502045

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '28 Aug 2020'	(b) (4) Amy Harrison (b) (4)	28 Aug 2020 13:40:29

US3502045

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Clinic (Clinic)'	Amy Harrison (b) (4)	28 Aug 2020 13:40:29

**US3502045**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:55:38**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User entered 'VISIT1'	System	28 Aug 2020 13:40:29

US3502045

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '28 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 13:29:38



US3502045

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:55:38

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '145094'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 13:29:38

US3502045

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:55:38

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 13:29:38

US3502045

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:55:38

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)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Amy Harrison (b) (4)	28 Aug 2020 13:41:01

US3502045

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:55:38

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)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'No (N)'	Amy Harrison (b) (4)	28 Aug 2020 13:41:01

**US3502045**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 07:55:38**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'No (N)'	Amy Harrison (b) (4)	28 Aug 2020 13:41:01

**US3502045**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 07:55:38**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'No (N)'	Amy Harrison (b) (4)	28 Aug 2020 13:41:01

US3502045

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:55:38

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'No (N)'	(b) (4) Amy Harrison (b) (4)	28 Aug 2020 13:41:01

**US3502045**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 07:55:38**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'No (N)'	Suzanne Fiorillo (b) (4)	29 Sep 2020 22:15:37
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:23:48
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:23:47



**US3502045**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 07:55:38**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered missing code ND - Not Done.	Josie Marshall (b) (4)	31 Aug 2020 19:49:40

**US3502045**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 07:55:38**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered missing code ND - Not Done.	Josie Marshall (b) (4)	31 Aug 2020 19:49:40

**US3502045**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 07:55:38**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered missing code ND - Not Done.	Josie Marshall (b) (4)	31 Aug 2020 19:49:40

US3502045

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:55:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered missing code ND - Not Done.	Josie Marshall (b) (4)	31 Aug 2020 19:49:40

US3502045

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User accepted default value 'Pre-Dose (PREDOSE)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:49:40

**US3502045**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Josie Marshall (b) (4)	31 Aug 2020 19:49:40

**US3502045**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:55:38**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '28 Aug 2020'	Josie Marshall (b) (4)	31 Aug 2020 19:49:40

**US3502045**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '07:45'	Josie Marshall (b) (4)	31 Aug 2020 19:49:40



**US3502045**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User entered '28 Aug 2020 07:45'	System	31 Aug 2020 19:49:40

US3502045

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '36.7' C	Josie Marshall (b) (4)	31 Aug 2020 19:49:40

US3502045

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Other (Other)'	Josie Marshall (b) (4)	31 Aug 2020 19:49:40

**US3502045**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:55:38**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'forehead'	Josie Marshall (b) (4)	31 Aug 2020 19:49:40

**US3502045**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '65'	Josie Marshall (b) (4)	31 Aug 2020 19:49:40

**US3502045**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User entered 'bpm'	System	31 Aug 2020 19:49:40

US3502045

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '14'	Josie Marshall (b) (4)	31 Aug 2020 19:49:40

**US3502045**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User entered 'breaths/min'	System	31 Aug 2020 19:49:40



US3502045

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '113'	Josie Marshall (b) (4)	31 Aug 2020 19:49:40

**US3502045**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User entered 'mmHg'	System	31 Aug 2020 19:49:40

US3502045

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '70'	Josie Marshall (b) (4)	31 Aug 2020 19:49:40

**US3502045**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User entered 'mmHg'	System	31 Aug 2020 19:49:40

**US3502045**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 07:55:38**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered missing code ND - Not Done.	Josie Marshall (b) (4)	31 Aug 2020 19:49:40

**US3502045**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 07:55:38**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered missing code ND - Not Done.	Josie Marshall (b) (4)	31 Aug 2020 19:49:40

US3502045

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User accepted default value 'Post-Dose (POSTDOSE)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:50:20

US3502045

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Josie Marshall (b) (4)	31 Aug 2020 19:50:20



US3502045

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '28 Aug 2020'	Josie Marshall (b) (4)	31 Aug 2020 19:50:20

**US3502045**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '08:54'	Josie Marshall (b) (4)	31 Aug 2020 19:50:20

**US3502045**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User entered '28 Aug 2020 08:54'	System	31 Aug 2020 19:50:20

US3502045

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '36.0' C	Josie Marshall (b) (4)	31 Aug 2020 19:50:20

US3502045

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Other (Other)'	Josie Marshall (b) (4)	31 Aug 2020 19:50:20

US3502045

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'forehead'	Josie Marshall (b) (4)	31 Aug 2020 19:50:20

**US3502045**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '64'	Josie Marshall (b) (4)	31 Aug 2020 19:50:20

**US3502045**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User entered 'bpm'	System	31 Aug 2020 19:50:20



**US3502045**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '14'	Josie Marshall (b) (4)	31 Aug 2020 19:50:20

**US3502045**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User entered 'breaths/min'	System	31 Aug 2020 19:50:20

US3502045

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '124'	Josie Marshall (b) (4)	31 Aug 2020 19:50:20

US3502045

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User entered 'mmHg'	System	31 Aug 2020 19:50:20

US3502045

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '65'	Josie Marshall (b) (4)	31 Aug 2020 19:50:20

US3502045

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User entered 'mmHg'	System	31 Aug 2020 19:50:20

**US3502045**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:55:38**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'No (N)'	Josie Marshall (b) (4)	31 Aug 2020 19:50:26

**US3502045**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:55:38**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered empty.	Josie Marshall (b) (4)	31 Aug 2020 19:50:26



US3502045

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	(b) (4) Amy Harrison (b) (4)	28 Aug 2020 14:23:22

US3502045

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered empty.	(b) (4) Amy Harrison (b) (4)	28 Aug 2020 14:23:22

US3502045

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

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)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered empty.	Amy Harrison (b) (4)	28 Aug 2020 14:23:22

**US3502045**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:55:38**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 14:23:22

US3502045

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '28 Aug 2020'	Amy Harrison (b) (4)	28 Aug 2020 14:23:22

US3502045

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '08:22'	(b) (4) Amy Harrison (b) (4)	28 Aug 2020 14:23:22

**US3502045**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:55:38**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User entered '28 Aug 2020 08:22'	System	28 Aug 2020 14:23:22

US3502045

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Left Arm (LEFT ARM)'	Amy Harrison (b) (4)	28 Aug 2020 14:23:22



US3502045

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User entered 'ONCE'	System	28 Aug 2020 14:23:22

US3502045

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 14:23:22

**US3502045**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:55:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Josie Marshall (b) (4)	31 Aug 2020 19:50:39

US3502045

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '28 Aug 2020'	Josie Marshall (b) (4)	31 Aug 2020 19:50:39

**US3502045**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:55:38**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '08:10'	Josie Marshall (b) (4)	31 Aug 2020 19:50:39

**US3502045**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:55:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User entered '28 Aug 2020 08:10'	System	31 Aug 2020 19:50:39

US3502045

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 07:55:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '28 Aug 2020'	Josie Marshall (b) (4)	31 Aug 2020 19:50:55

**US3502045**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:50:55



**US3502045**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Josie Marshall (b) (4)	31 Aug 2020 19:50:55

**US3502045**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '08:17'	Josie Marshall (b) (4)	31 Aug 2020 19:50:55

**US3502045**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User entered '28 Aug 2020 08:17'	System	31 Aug 2020 19:50:55

**US3502045**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:50:55

**US3502045**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'No (N)'	Josie Marshall (b) (4)	31 Aug 2020 19:50:55

**US3502045**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered empty.	Josie Marshall (b) (4)	31 Aug 2020 19:50:55

**US3502045**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User entered empty.	System	31 Aug 2020 19:50:55

US3502045

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Josie Marshall (b) (4)	31 Aug 2020 19:51:00



**US3502045**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:55:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User entered '1'	System	31 Aug 2020 19:51:00

US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	28 Aug 2020 14:23:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 14:23:22

US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-28T08:47:36', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '4216fbf6-80a9-48cc-bb87-2c21b01280d6' User entered 'Yes (Y)'	System	28 Aug 2020 14:48:09
	System	28 Aug 2020 14:48:09

US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-28T08:47:58', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '4216fbf6-80a9-48cc-bb87-2c21b01280d6' User entered '97.5'	System	28 Aug 2020 14:48:09
	System	28 Aug 2020 14:48:09

US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-28T08:48:01', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '4216fbf6-80a9-48cc-bb87-2c21b01280d6'	System	28 Aug 2020 14:48:09
User entered 'No (N)'	System	28 Aug 2020 14:48:09

**US3502045**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-28T08:48:08', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '4216fbf6-80a9-48cc-bb87-2c21b01280d6' User entered '28 Aug 2020 08:48'	System	28 Aug 2020 14:48:09
	System	28 Aug 2020 14:48:09

**US3502045**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '28 Aug 2020 08:42'	System	28 Aug 2020 14:23:22

**US3502045**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '28 Aug 2020 11:12'	System	28 Aug 2020 14:23:22



US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	28 Aug 2020 14:23:22
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 14:23:22

US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14

US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14

US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14

US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14

US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14

US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14

**US3502045**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '28 Aug 2020 12:07'	System	28 Aug 2020 14:23:22



**US3502045**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 14:23:22

US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	28 Aug 2020 14:23:22
User entered 'Day 2'	System	28 Aug 2020 14:23:22

**US3502045**

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

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

**Generated On: 10 Jun 2021 07:55:38**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-29T13:07:35', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'fef2c62-a68b-4ddd-a7fd-155d08accc00'	System	29 Aug 2020 19:07:54
User entered 'Yes (Y)'	System	29 Aug 2020 19:07:54

US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-29T13:07:43', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'fef2c62-a68b-4ddd-a7fd-155d08accc00' User entered '97.3'	System	29 Aug 2020 19:07:54
	System	29 Aug 2020 19:07:54

US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-29T13:07:46', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'fef2c62-a68b-4ddd-a7fd-155d08accc00'	System	29 Aug 2020 19:07:54
User entered 'No (N)'	System	29 Aug 2020 19:07:54

**US3502045**

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

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

**Generated On: 10 Jun 2021 07:55:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-29T13:07:53', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'fef2c62-a68b-4ddd-a7fd-155d08accc00'	System	29 Aug 2020 19:07:54
User entered '29 Aug 2020 13:07'	System	29 Aug 2020 19:07:54

**US3502045**

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

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

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 14:23:22

**US3502045**

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

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

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 14:23:22



US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	28 Aug 2020 14:23:22
User entered 'Day 3'	System	28 Aug 2020 14:23:22

US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14

US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14

US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14

US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14

US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:55:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14

**US3502045**

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

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14

**US3502045**

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

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 14:23:22



**US3502045**

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

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 14:23:22

US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	28 Aug 2020 14:23:22
User entered 'Day 4'	System	28 Aug 2020 14:23:22

US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-31T19:50:39', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'b9879cab-2b77-4372-9e02-c8f73c94c3cf' User entered 'Yes (Y)'	System	01 Sep 2020 01:52:21
	System	01 Sep 2020 01:52:21

US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-31T19:52:10', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'b9879cab-2b77-4372-9e02-c8f73c94c3cf' User entered '97.2'	System	01 Sep 2020 01:52:21
	System	01 Sep 2020 01:52:21

US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-31T19:52:15', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'b9879cab-2b77-4372-9e02-c8f73c94c3cf' User entered 'No (N)'	System	01 Sep 2020 01:52:21
	System	01 Sep 2020 01:52:21

US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:55:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-31T19:52:19', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'b9879cab-2b77-4372-9e02-c8f73c94c3cf' User entered '31 Aug 2020 19:52'	System	01 Sep 2020 01:52:21
	System	01 Sep 2020 01:52:21

**US3502045**

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

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 14:23:22

**US3502045**

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

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 14:23:22



**US3502045**

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

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	28 Aug 2020 14:23:22
User entered 'Day 5'	System	28 Aug 2020 14:23:22

US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-01T22:20:47', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '2e0b47fa-dcf8-42e5-9ae8-5c6da6fbeca8' User entered 'Yes (Y)'	System	02 Sep 2020 04:21:05
	System	02 Sep 2020 04:21:05

US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-01T22:20:55', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '2e0b47fa-dcf8-42e5-9ae8-5c6da6fbeca8' User entered '97.6'	System	02 Sep 2020 04:21:05
	System	02 Sep 2020 04:21:05

US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-01T22:20:58', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '2e0b47fa-dcf8-42e5-9ae8-5c6da6fbeca8'	System	02 Sep 2020 04:21:05
User entered 'No (N)'	System	02 Sep 2020 04:21:05

**US3502045**

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

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-01T22:21:03', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '2e0b47fa-dcf8-42e5-9ae8-5c6da6fbeca8'	System	02 Sep 2020 04:21:05
User entered '01 Sep 2020 22:21'	System	02 Sep 2020 04:21:05

**US3502045**

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

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 14:23:22

**US3502045**

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

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 14:23:22

US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	28 Aug 2020 14:23:22
User entered 'Day 6'	System	28 Aug 2020 14:23:22



**US3502045**

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

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 07:55:38**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-02T16:31:59', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '42b7ed0c-340f-4f3d-adff-509adbc9d12b' User entered 'Yes (Y)'	System	02 Sep 2020 22:32:21
	System	02 Sep 2020 22:32:21

US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-02T16:32:08', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '42b7ed0c-340f-4f3d-adff-509adbc9d12b' User entered '97.2'	System	02 Sep 2020 22:32:21
	System	02 Sep 2020 22:32:21

US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-02T16:32:11', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '42b7ed0c-340f-4f3d-adff-509adbc9d12b'	System	02 Sep 2020 22:32:21
User entered 'No (N)'	System	02 Sep 2020 22:32:21

**US3502045**

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

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-02T16:32:15', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '42b7ed0c-340f-4f3d-adff-509adbc9d12b' User entered '02 Sep 2020 16:32'	System	02 Sep 2020 22:32:21
	System	02 Sep 2020 22:32:21

**US3502045**

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

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 14:23:22

**US3502045**

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

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 14:23:22

**US3502045**

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

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	28 Aug 2020 14:23:22
User entered 'Day 7'	System	28 Aug 2020 14:23:22

US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-03T21:31:12', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'faf53d93-6816-4551-a20f-fc57d7d9f4e0'	System	04 Sep 2020 03:32:04
User entered 'Yes (Y)'	System	04 Sep 2020 03:32:04



US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-03T21:31:51', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'faf53d93-6816-4551-a20f-fc57d7d9f4e0'	System	04 Sep 2020 03:32:04
User entered '97.8'	System	04 Sep 2020 03:32:04

US3502045

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-03T21:31:55', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'faf53d93-6816-4551-a20f-fc57d7d9f4e0'	System	04 Sep 2020 03:32:04
User entered 'No (N)'	System	04 Sep 2020 03:32:04

**US3502045**

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

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-03T21:32:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'faf53d93-6816-4551-a20f-fc57d7d9f4e0'	System	04 Sep 2020 03:32:04
User entered '03 Sep 2020 21:32'	System	04 Sep 2020 03:32:04

**US3502045**

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

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 14:23:22

**US3502045**

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

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 14:23:22

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	28 Aug 2020 14:23:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 14:23:22

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-28T08:48:34', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'cf190358-2efa-4889-a85e-55a39c532861'	System	28 Aug 2020 14:48:54
User entered 'None (1)'	System	28 Aug 2020 14:48:54

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-28T08:48:38', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'cf190358-2efa-4889-a85e-55a39c532861'	System	28 Aug 2020 14:48:54
User entered 'No (N)'	System	28 Aug 2020 14:48:54



US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-28T08:48:41', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'cf190358-2efa-4889-a85e-55a39c532861'	System	28 Aug 2020 14:48:54
User entered 'No (N)'	System	28 Aug 2020 14:48:54

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-28T08:48:45', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'cf190358-2efa-4889-a85e-55a39c532861'	System	28 Aug 2020 14:48:54
User entered 'None (1)'	System	28 Aug 2020 14:48:54

**US3502045**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-28T08:48:49', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'cf190358-2efa-4889-a85e-55a39c532861' User entered '28 Aug 2020 08:48'	System	28 Aug 2020 14:48:54
	System	28 Aug 2020 14:48:54

**US3502045**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '28 Aug 2020 08:42'	System	28 Aug 2020 14:23:22

**US3502045**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '28 Aug 2020 11:12'	System	28 Aug 2020 14:23:22

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	28 Aug 2020 14:23:22
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 14:23:22

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14



US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14

**US3502045**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14

**US3502045**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '28 Aug 2020 12:07'	System	28 Aug 2020 14:23:22

**US3502045**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 14:23:22

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	28 Aug 2020 14:23:22
User entered 'Day 2'	System	28 Aug 2020 14:23:22



US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-29T13:08:08', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '063bf6de-9372-40e0-8aba-078120ba9519'	System	29 Aug 2020 19:15:00
User entered 'Does not interfere with activity (2)'	System	29 Aug 2020 19:15:00

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-29T13:08:18', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '063bf6de-9372-40e0-8aba-078120ba9519' User entered 'No (N)'	System	29 Aug 2020 19:15:00
	System	29 Aug 2020 19:15:00

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-29T13:14:38', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '063bf6de-9372-40e0-8aba-078120ba9519' User entered 'No (N)'	System	29 Aug 2020 19:15:00
	System	29 Aug 2020 19:15:00

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-29T13:14:46', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '063bf6de-9372-40e0-8aba-078120ba9519' User entered 'None (1)'	System	29 Aug 2020 19:15:00
	System	29 Aug 2020 19:15:00

**US3502045**

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

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-29T13:14:59', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '063bf6de-9372-40e0-8aba-078120ba9519' User entered '29 Aug 2020 13:14'	System	29 Aug 2020 19:15:00
	System	29 Aug 2020 19:15:00

**US3502045**

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

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 14:23:22

**US3502045**

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

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 14:23:22

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	28 Aug 2020 14:23:22
User entered 'Day 3'	System	28 Aug 2020 14:23:22



US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14

**US3502045**

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

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14

**US3502045**

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

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 14:23:22



**US3502045**

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

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 14:23:22

**US3502045**

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

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	28 Aug 2020 14:23:22
User entered 'Day 4'	System	28 Aug 2020 14:23:22

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-31T19:52:26', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '75808e3b-5bec-4218-9680-c70fbde8d7f7'	System	01 Sep 2020 01:52:41
User entered 'None (1)'	System	01 Sep 2020 01:52:41

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-31T19:52:29', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '75808e3b-5bec-4218-9680-c70fbde8d7f7'	System	01 Sep 2020 01:52:41
User entered 'No (N)'	System	01 Sep 2020 01:52:41

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-31T19:52:31', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '75808e3b-5bec-4218-9680-c70fbde8d7f7'	System	01 Sep 2020 01:52:41
User entered 'No (N)'	System	01 Sep 2020 01:52:41

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-31T19:52:34', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '75808e3b-5bec-4218-9680-c70fbde8d7f7'	System	01 Sep 2020 01:52:41
User entered 'None (1)'	System	01 Sep 2020 01:52:41

**US3502045**

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

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-31T19:52:38', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '75808e3b-5bec-4218-9680-c70fbde8d7f7'	System	01 Sep 2020 01:52:41
User entered '31 Aug 2020 19:52'	System	01 Sep 2020 01:52:41

**US3502045**

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

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 14:23:22



**US3502045**

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

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 14:23:22

**US3502045**

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

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	28 Aug 2020 14:23:22
User entered 'Day 5'	System	28 Aug 2020 14:23:22

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-01T22:21:12', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'eef084f3-a83b-4aa8-9220-82bf5ae5571e'	System	02 Sep 2020 04:22:08
User entered 'None (1)'	System	02 Sep 2020 04:22:08

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-01T22:21:34', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'eef084f3-a83b-4aa8-9220-82bf5ae5571e' User entered 'No (N)'	System	02 Sep 2020 04:22:08
	System	02 Sep 2020 04:22:08

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-01T22:21:38', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'eef084f3-a83b-4aa8-9220-82bf5ae5571e' User entered 'No (N)'	System	02 Sep 2020 04:22:08
	System	02 Sep 2020 04:22:08

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-01T22:21:57', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'eef084f3-a83b-4aa8-9220-82bf5ae5571e' User entered 'Does not interfere with activity (2)'	System	02 Sep 2020 04:22:08
	System	02 Sep 2020 04:22:08

**US3502045**

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

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-01T22:22:02', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'eef084f3-a83b-4aa8-9220-82bf5ae5571e' User entered '01 Sep 2020 22:22'	System	02 Sep 2020 04:22:08
	System	02 Sep 2020 04:22:08

**US3502045**

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

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 14:23:22



**US3502045**

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

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 14:23:22

**US3502045**

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

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	28 Aug 2020 14:23:22
User entered 'Day 6'	System	28 Aug 2020 14:23:22

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-02T16:32:21', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'da8c63ea-4f1a-4234-a216-f7aa3250fbb1' User entered 'None (1)'	System	02 Sep 2020 22:32:39
	System	02 Sep 2020 22:32:39

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-02T16:32:26', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'da8c63ea-4f1a-4234-a216-f7aa3250fbb1' User entered 'No (N)'	System	02 Sep 2020 22:32:39
	System	02 Sep 2020 22:32:39

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-02T16:32:29', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'da8c63ea-4f1a-4234-a216-f7aa3250fbb1' User entered 'No (N)'	System	02 Sep 2020 22:32:39
	System	02 Sep 2020 22:32:39

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-02T16:32:34', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'da8c63ea-4f1a-4234-a216-f7aa3250fbb1' User entered 'None (1)'	System	02 Sep 2020 22:32:39
	System	02 Sep 2020 22:32:39

**US3502045**

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

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-02T16:32:38', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'da8c63ea-4f1a-4234-a216-f7aa3250fbb1' User entered '02 Sep 2020 16:32'	System	02 Sep 2020 22:32:39
	System	02 Sep 2020 22:32:39

**US3502045**

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

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 14:23:22



**US3502045**

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

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 14:23:22

**US3502045**

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

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	28 Aug 2020 14:23:22
User entered 'Day 7'	System	28 Aug 2020 14:23:22

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-03T21:32:06', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '452a5952-39aa-4c41-b2b1-ebf4382a5257'	System	04 Sep 2020 03:32:33
User entered 'None (1)'	System	04 Sep 2020 03:32:33

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-03T21:32:13', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '452a5952-39aa-4c41-b2b1-ebf4382a5257'	System	04 Sep 2020 03:32:33
User entered 'No (N)'	System	04 Sep 2020 03:32:33

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-03T21:32:16', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '452a5952-39aa-4c41-b2b1-ebf4382a5257' User entered 'No (N)'	System	04 Sep 2020 03:32:33
	System	04 Sep 2020 03:32:33

US3502045

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-03T21:32:26', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '452a5952-39aa-4c41-b2b1-ebf4382a5257'	System	04 Sep 2020 03:32:33
User entered 'None (1)'	System	04 Sep 2020 03:32:33

**US3502045**

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

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-03T21:32:30', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '452a5952-39aa-4c41-b2b1-ebf4382a5257' User entered '03 Sep 2020 21:32'	System	04 Sep 2020 03:32:33
	System	04 Sep 2020 03:32:33

**US3502045**

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

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 14:23:22



**US3502045**

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

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 14:23:22

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	28 Aug 2020 14:23:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 14:23:22

**US3502045**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:55:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-28T08:49:03', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'b5a00d7a-104a-47c7-8866-de4e0ffc9c2c'	System	28 Aug 2020 14:49:53
User entered 'No interference with activity (1)'	System	28 Aug 2020 14:49:53

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-28T08:49:08', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'b5a00d7a-104a-47c7-8866-de4e0ffc9c2c' User entered 'None (0)'	System	28 Aug 2020 14:49:53
	System	28 Aug 2020 14:49:53

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-28T08:49:12', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'b5a00d7a-104a-47c7-8866-de4e0ffc9c2c' User entered 'None (0)'	System	28 Aug 2020 14:49:53
	System	28 Aug 2020 14:49:53

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-28T08:49:15', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'b5a00d7a-104a-47c7-8866-de4e0ffc9c2c' User entered 'None (0)'	System	28 Aug 2020 14:49:53
	System	28 Aug 2020 14:49:53

**US3502045**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:55:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-28T08:49:22', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'b5a00d7a-104a-47c7-8866-de4e0ffc9c2c' User entered 'None (0)'	System	28 Aug 2020 14:49:53
	System	28 Aug 2020 14:49:53

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-28T08:49:24', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'b5a00d7a-104a-47c7-8866-de4e0ffc9c2c' User entered 'None (0)'	System	28 Aug 2020 14:49:53
	System	28 Aug 2020 14:49:53



US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-28T08:49:41', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'b5a00d7a-104a-47c7-8866-de4e0ffc9c2c' User entered 'No (N)'	System	28 Aug 2020 14:49:53
	System	28 Aug 2020 14:49:53

**US3502045**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-28T08:49:51', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'b5a00d7a-104a-47c7-8866-de4e0ffc9c2c' User entered '28 Aug 2020 08:49'	System	28 Aug 2020 14:49:53
	System	28 Aug 2020 14:49:53

**US3502045**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '28 Aug 2020 08:42'	System	28 Aug 2020 14:23:22

**US3502045**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '28 Aug 2020 11:12'	System	28 Aug 2020 14:23:22

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	28 Aug 2020 14:23:22
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 14:23:22

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14

**US3502045**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:55:38**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14



US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14

**US3502045**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:55:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14

**US3502045**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:55:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14

**US3502045**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14

**US3502045**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '28 Aug 2020 12:07'	System	28 Aug 2020 14:23:22

**US3502045**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 14:23:22

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	28 Aug 2020 14:23:22
User entered 'Day 2'	System	28 Aug 2020 14:23:22



**US3502045**

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

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

**Generated On: 10 Jun 2021 07:55:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-29T13:15:14', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'b5d4a2d9-09f8-46ba-b9cf-7eac13035f52'	System	29 Aug 2020 19:15:51
User entered 'No interference with activity (1)'	System	29 Aug 2020 19:15:51

**US3502045**

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

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

**Generated On: 10 Jun 2021 07:55:38**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-29T13:15:20', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'b5d4a2d9-09f8-46ba-b9cf-7eac13035f52'	System	29 Aug 2020 19:15:51
User entered 'None (0)'	System	29 Aug 2020 19:15:51

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:55:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-29T13:15:24', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'b5d4a2d9-09f8-46ba-b9cf-7eac13035f52'	System	29 Aug 2020 19:15:51
User entered 'None (0)'	System	29 Aug 2020 19:15:51

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:55:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-29T13:15:27', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'b5d4a2d9-09f8-46ba-b9cf-7eac13035f52'	System	29 Aug 2020 19:15:51
User entered 'None (0)'	System	29 Aug 2020 19:15:51

**US3502045**

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

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

**Generated On: 10 Jun 2021 07:55:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-29T13:15:30', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'b5d4a2d9-09f8-46ba-b9cf-7eac13035f52'	System	29 Aug 2020 19:15:51
User entered 'None (0)'	System	29 Aug 2020 19:15:51

**US3502045**

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

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

**Generated On: 10 Jun 2021 07:55:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-29T13:15:32', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'b5d4a2d9-09f8-46ba-b9cf-7eac13035f52'	System	29 Aug 2020 19:15:51
User entered 'None (0)'	System	29 Aug 2020 19:15:51

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-29T13:15:37', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'b5d4a2d9-09f8-46ba-b9cf-7eac13035f52'	System	29 Aug 2020 19:15:51
User entered 'No (N)'	System	29 Aug 2020 19:15:51

**US3502045**

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

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

**Generated On: 10 Jun 2021 07:55:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-29T13:15:49', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'b5d4a2d9-09f8-46ba-b9cf-7eac13035f52'	System	29 Aug 2020 19:15:51
User entered '29 Aug 2020 13:15'	System	29 Aug 2020 19:15:51



**US3502045**

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

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

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 14:23:22

**US3502045**

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

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

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 14:23:22

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	28 Aug 2020 14:23:22
User entered 'Day 3'	System	28 Aug 2020 14:23:22

**US3502045**

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

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:55:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14

**US3502045**

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

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:55:38**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:55:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:55:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:55:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14



**US3502045**

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

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:55:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14

**US3502045**

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

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14

**US3502045**

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

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 14:23:22

**US3502045**

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

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 14:23:22

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	28 Aug 2020 14:23:22
User entered 'Day 4'	System	28 Aug 2020 14:23:22

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:55:38

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-31T19:53:01', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'a289830a-dd79-4ccf-b58e-6407e51790bb'	System	01 Sep 2020 01:53:29
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	01 Sep 2020 01:53:29

**US3502045**

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

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:55:38**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-31T19:53:04', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'a289830a-dd79-4ccf-b58e-6407e51790bb' User entered 'None (0)'	System	01 Sep 2020 01:53:29
	System	01 Sep 2020 01:53:29



US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:55:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-31T19:53:06', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'a289830a-dd79-4ccf-b58e-6407e51790bb' User entered 'None (0)'	System	01 Sep 2020 01:53:29
	System	01 Sep 2020 01:53:29

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:55:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-31T19:53:09', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'a289830a-dd79-4ccf-b58e-6407e51790bb' User entered 'None (0)'	System	01 Sep 2020 01:53:29
	System	01 Sep 2020 01:53:29

**US3502045**

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

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:55:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-31T19:53:11', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'a289830a-dd79-4ccf-b58e-6407e51790bb' User entered 'None (0)'	System	01 Sep 2020 01:53:29
	System	01 Sep 2020 01:53:29

**US3502045**

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

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:55:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-31T19:53:14', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'a289830a-dd79-4ccf-b58e-6407e51790bb' User entered 'None (0)'	System	01 Sep 2020 01:53:29
	System	01 Sep 2020 01:53:29

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-31T19:53:17', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'a289830a-dd79-4ccf-b58e-6407e51790bb' User entered 'No (N)'	System	01 Sep 2020 01:53:29
	System	01 Sep 2020 01:53:29

**US3502045**

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

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-08-31T19:53:27', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'a289830a-dd79-4ccf-b58e-6407e51790bb' User entered '31 Aug 2020 19:53'	System	01 Sep 2020 01:53:29
	System	01 Sep 2020 01:53:29

**US3502045**

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

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 14:23:22

**US3502045**

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

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 14:23:22



US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	28 Aug 2020 14:23:22
User entered 'Day 5'	System	28 Aug 2020 14:23:22

**US3502045**

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

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:55:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-01T22:22:11', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '27837500-ec78-44c1-9f14-7edfc3e05d27'	System	02 Sep 2020 04:22:43
User entered 'No interference with activity (1)'	System	02 Sep 2020 04:22:43

**US3502045**

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

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:55:38**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-01T22:22:15', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '27837500-ec78-44c1-9f14-7edfc3e05d27' User entered 'None (0)'	System	02 Sep 2020 04:22:43
	System	02 Sep 2020 04:22:43

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:55:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-01T22:22:17', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '27837500-ec78-44c1-9f14-7edfc3e05d27' User entered 'None (0)'	System	02 Sep 2020 04:22:43
	System	02 Sep 2020 04:22:43

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:55:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-01T22:22:20', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '27837500-ec78-44c1-9f14-7edfc3e05d27' User entered 'None (0)'	System	02 Sep 2020 04:22:43
	System	02 Sep 2020 04:22:43

**US3502045**

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

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:55:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-01T22:22:25', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '27837500-ec78-44c1-9f14-7edfc3e05d27'	System	02 Sep 2020 04:22:43
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	02 Sep 2020 04:22:43

**US3502045**

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

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:55:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-01T22:22:28', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '27837500-ec78-44c1-9f14-7edfc3e05d27' User entered 'None (0)'	System	02 Sep 2020 04:22:43
	System	02 Sep 2020 04:22:43

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-01T22:22:30', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '27837500-ec78-44c1-9f14-7edfc3e05d27'	System	02 Sep 2020 04:22:43
User entered 'No (N)'	System	02 Sep 2020 04:22:43



**US3502045**

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

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-01T22:22:39', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '27837500-ec78-44c1-9f14-7edfc3e05d27'	System	02 Sep 2020 04:22:43
User entered '01 Sep 2020 22:22'	System	02 Sep 2020 04:22:43

**US3502045**

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

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 14:23:22

**US3502045**

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

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 14:23:22

**US3502045**

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

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	28 Aug 2020 14:23:22
User entered 'Day 6'	System	28 Aug 2020 14:23:22

**US3502045**

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

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:55:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-02T16:32:45', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '0d1628c4-ea32-444f-8014-506fdd2b0c9f'	System	02 Sep 2020 22:33:09
User entered 'No interference with activity (1)'	System	02 Sep 2020 22:33:09

**US3502045**

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

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:55:38**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-02T16:32:50', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '0d1628c4-ea32-444f-8014-506fdd2b0c9f'	System	02 Sep 2020 22:33:09
User entered 'No interference with activity (1)'	System	02 Sep 2020 22:33:09

**US3502045**

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

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:55:38**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-02T16:32:53', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '0d1628c4-ea32-444f-8014-506fdd2b0c9f' User entered 'None (0)'	System	02 Sep 2020 22:33:09
	System	02 Sep 2020 22:33:09

**US3502045**

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

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:55:38**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-02T16:32:56', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '0d1628c4-ea32-444f-8014-506fdd2b0c9f' User entered 'None (0)'	System	02 Sep 2020 22:33:09
	System	02 Sep 2020 22:33:09



**US3502045**

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

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:55:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-02T16:32:59', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '0d1628c4-ea32-444f-8014-506fdd2b0c9f' User entered 'None (0)'	System	02 Sep 2020 22:33:09
	System	02 Sep 2020 22:33:09

**US3502045**

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

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:55:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-02T16:33:01', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '0d1628c4-ea32-444f-8014-506fdd2b0c9f' User entered 'None (0)'	System	02 Sep 2020 22:33:09
	System	02 Sep 2020 22:33:09

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-02T16:33:04', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '0d1628c4-ea32-444f-8014-506fdd2b0c9f' User entered 'No (N)'	System	02 Sep 2020 22:33:09
	System	02 Sep 2020 22:33:09

**US3502045**

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

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-02T16:33:07', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '0d1628c4-ea32-444f-8014-506fdd2b0c9f' User entered '02 Sep 2020 16:33'	System	02 Sep 2020 22:33:09
	System	02 Sep 2020 22:33:09

**US3502045**

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

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 14:23:22

**US3502045**

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

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 14:23:22

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	28 Aug 2020 14:23:22
User entered 'Day 7'	System	28 Aug 2020 14:23:22

**US3502045**

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

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:55:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-03T21:33:05', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '5b04e31f-c3fa-48fb-9004-2a61d38c2d73'	System	04 Sep 2020 03:33:53
User entered 'No interference with activity (1)'	System	04 Sep 2020 03:33:53



US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:55:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-03T21:33:09', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '5b04e31f-c3fa-48fb-9004-2a61d38c2d73'	System	04 Sep 2020 03:33:53
User entered 'No interference with activity (1)'	System	04 Sep 2020 03:33:53

**US3502045**

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

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:55:38**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-03T21:33:12', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '5b04e31f-c3fa-48fb-9004-2a61d38c2d73' User entered 'None (0)'	System	04 Sep 2020 03:33:53
	System	04 Sep 2020 03:33:53

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:55:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-03T21:33:15', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '5b04e31f-c3fa-48fb-9004-2a61d38c2d73' User entered 'None (0)'	System	04 Sep 2020 03:33:53
	System	04 Sep 2020 03:33:53

**US3502045**

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

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:55:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-03T21:33:20', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '5b04e31f-c3fa-48fb-9004-2a61d38c2d73'	System	04 Sep 2020 03:33:53
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	04 Sep 2020 03:33:53

**US3502045**

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

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:55:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-03T21:33:43', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '5b04e31f-c3fa-48fb-9004-2a61d38c2d73' User entered 'None (0)'	System	04 Sep 2020 03:33:53
	System	04 Sep 2020 03:33:53

US3502045

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-03T21:33:47', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '5b04e31f-c3fa-48fb-9004-2a61d38c2d73'	System	04 Sep 2020 03:33:53
User entered 'No (N)'	System	04 Sep 2020 03:33:53

**US3502045**

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

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-03T21:33:51', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '5b04e31f-c3fa-48fb-9004-2a61d38c2d73' User entered '03 Sep 2020 21:33'	System	04 Sep 2020 03:33:53
	System	04 Sep 2020 03:33:53

**US3502045**

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

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 14:23:22



**US3502045**

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

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 14:23:22

US3502045

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	02 Sep 2020 22:33:09
User entered 'Day 8'	System	02 Sep 2020 22:33:09

**US3502045**

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

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 07:55:38**

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-04T19:55:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'cdb1fb4f-864a-4cb3-877f-36c1d2acb98c'	System	05 Sep 2020 01:55:08
User entered 'No interference with activity (1)'	System	05 Sep 2020 01:55:08

**US3502045**

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

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-04T19:55:07', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'cdb1fb4f-864a-4cb3-877f-36c1d2acb98c' User entered '04 Sep 2020 19:55'	System	05 Sep 2020 01:55:08
	System	05 Sep 2020 01:55:08

**US3502045**

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

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 22:33:09

**US3502045**

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

**Form: Headache\_Day(8)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 22:33:09

**US3502045**

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

**Form: Headache\_Day(9)**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	04 Sep 2020 03:33:53
User entered 'Day 9'	System	04 Sep 2020 03:33:53

US3502045

Folder: Diary Dose 1 (1)

Form: Headache\_Day(9)

Generated On: 10 Jun 2021 07:55:38

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-05T12:59:58', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'e1442aae-61b9-41d1-849f-f4c72562c58b'	System	05 Sep 2020 19:00:09
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	05 Sep 2020 19:00:09



**US3502045**

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

**Form: Headache\_Day(9)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-05T13:00:06', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'e1442aae-61b9-41d1-849f-f4c72562c58b' User entered '05 Sep 2020 13:00'	System	05 Sep 2020 19:00:09
	System	05 Sep 2020 19:00:09

**US3502045**

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

**Form: Headache\_Day(9)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 03:33:53

**US3502045**

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

**Form: Headache\_Day(9)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 03:33:53

US3502045

Folder: Diary Dose 1 (1)

Form: Headache\_Day(10)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	05 Sep 2020 01:55:08
User entered 'Day 10'	System	05 Sep 2020 01:55:08

**US3502045**

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

**Form: Headache\_Day(10)**

**Generated On: 10 Jun 2021 07:55:38**

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-07T10:14:24', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '174c917d-7afb-4f84-adf6-9ab80dc50908' User entered 'None (0)'	System	07 Sep 2020 16:14:33
	System	07 Sep 2020 16:14:33

**US3502045**

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

**Form: Headache\_Day(10)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-07T10:14:29', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '174c917d-7afb-4f84-adf6-9ab80dc50908'	System	07 Sep 2020 16:14:33
User entered '07 Sep 2020 10:14'	System	07 Sep 2020 16:14:33

**US3502045**

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

**Form: Headache\_Day(10)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 01:55:08

**US3502045**

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

**Form: Headache\_Day(10)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 01:55:08



**US3502045**

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

**Form: Fatigue\_Day(8)**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	02 Sep 2020 22:33:09
User entered 'Day 8'	System	02 Sep 2020 22:33:09

**US3502045**

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

**Form: Fatigue\_Day(8)**

**Generated On: 10 Jun 2021 07:55:38**

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-04T19:55:25', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '449fe752-d4e4-40a3-8625-d34f2cee4652'	System	05 Sep 2020 01:55:33
User entered 'No interference with activity (1)'	System	05 Sep 2020 01:55:33

**US3502045**

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

**Form: Fatigue\_Day(8)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-04T19:55:29', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '449fe752-d4e4-40a3-8625-d34f2cee4652'	System	05 Sep 2020 01:55:33
User entered '04 Sep 2020 19:55'	System	05 Sep 2020 01:55:33

**US3502045**

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

**Form: Fatigue\_Day(8)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 22:33:09

**US3502045**

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

**Form: Fatigue\_Day(8)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 22:33:09

US3502045

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(9)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	04 Sep 2020 03:33:53
User entered 'Day 9'	System	04 Sep 2020 03:33:53

**US3502045**

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

**Form: Fatigue\_Day(9)**

**Generated On: 10 Jun 2021 07:55:38**

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-05T13:00:46', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '54558609-34f9-4ac1-b80d-2cc7369e87d8'	System	05 Sep 2020 19:00:50
User entered 'No interference with activity (1)'	System	05 Sep 2020 19:00:50

**US3502045**

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

**Form: Fatigue\_Day(9)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-05T13:00:49', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '54558609-34f9-4ac1-b80d-2cc7369e87d8' User entered '05 Sep 2020 13:00'	System	05 Sep 2020 19:00:50
	System	05 Sep 2020 19:00:50



**US3502045**

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

**Form: Fatigue\_Day(9)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 03:33:53

**US3502045**

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

**Form: Fatigue\_Day(9)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 03:33:53

US3502045

Folder: Diary Dose 1 (1)

Form: Fatigue\_Day(10)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	05 Sep 2020 01:55:33
User entered 'Day 10'	System	05 Sep 2020 01:55:33

**US3502045**

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

**Form: Fatigue\_Day(10)**

**Generated On: 10 Jun 2021 07:55:38**

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-07T10:14:33', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '4c22d7a3-5187-42f5-8c9e-01963d9b1409' User entered 'None (0)'	System	07 Sep 2020 16:14:42
	System	07 Sep 2020 16:14:42

**US3502045**

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

**Form: Fatigue\_Day(10)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-07T10:14:40', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '4c22d7a3-5187-42f5-8c9e-01963d9b1409' User entered '07 Sep 2020 10:14'	System	07 Sep 2020 16:14:42
	System	07 Sep 2020 16:14:42

**US3502045**

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

**Form: Fatigue\_Day(10)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 01:55:33

**US3502045**

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

**Form: Fatigue\_Day(10)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 01:55:33

US3502045

Folder: Diary Dose 1 (1)

Form: Nausea\_Day(8)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	04 Sep 2020 03:33:53
User entered 'Day 8'	System	04 Sep 2020 03:33:53



**US3502045**

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

**Form: Nausea\_Day(8)**

**Generated On: 10 Jun 2021 07:55:38**

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-04T19:55:34', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '8170a974-43fe-4d44-8603-bd899bc6c71d'	System	05 Sep 2020 01:55:40
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	05 Sep 2020 01:55:40

**US3502045**

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

**Form: Nausea\_Day(8)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-04T19:55:37', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '8170a974-43fe-4d44-8603-bd899bc6c71d' User entered '04 Sep 2020 19:55'	System	05 Sep 2020 01:55:40
	System	05 Sep 2020 01:55:40

**US3502045**

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

**Form: Nausea\_Day(8)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '04 Sep 2020 12:00'	System	04 Sep 2020 03:33:53

**US3502045**

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

**Form: Nausea\_Day(8)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 03:33:53

**US3502045**

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

**Form: Nausea\_Day(9)**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	04 Sep 2020 03:33:53
User entered 'Day 9'	System	04 Sep 2020 03:33:53

**US3502045**

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

**Form: Nausea\_Day(9)**

**Generated On: 10 Jun 2021 07:55:38**

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-05T13:00:56', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '70f22cf2-0785-4e37-8522-b59efb900929' User entered 'None (0)'	System	05 Sep 2020 19:01:01
	System	05 Sep 2020 19:01:01

**US3502045**

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

**Form: Nausea\_Day(9)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-05T13:00:59', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '70f22cf2-0785-4e37-8522-b59efb900929' User entered '05 Sep 2020 13:00'	System	05 Sep 2020 19:01:01
	System	05 Sep 2020 19:01:01

**US3502045**

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

**Form: Nausea\_Day(9)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 03:33:53



**US3502045**

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

**Form: Nausea\_Day(9)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 03:33:53

**US3502045**

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

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	02 Sep 2020 22:33:09
User entered 'Day 8'	System	02 Sep 2020 22:33:09

US3502045

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-04T19:55:41', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '31b5e908-5a4f-418b-94cc-484c2f8c5f94'	System	05 Sep 2020 01:55:45
User entered 'No (N)'	System	05 Sep 2020 01:55:45

**US3502045**

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

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-04T19:55:43', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '31b5e908-5a4f-418b-94cc-484c2f8c5f94'	System	05 Sep 2020 01:55:45
User entered '04 Sep 2020 19:55'	System	05 Sep 2020 01:55:45

**US3502045**

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

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 22:33:09

**US3502045**

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

**Form: Medical Attention\_Day(8)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 22:33:09

US3502045

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	04 Sep 2020 03:33:53
User entered 'Day 9'	System	04 Sep 2020 03:33:53

US3502045

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-05T13:01:03', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '0e13f9bf-8c52-451f-88ec-c507cc971c67'	System	05 Sep 2020 19:01:10
User entered 'No (N)'	System	05 Sep 2020 19:01:10



**US3502045**

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

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-05T13:01:05', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '0e13f9bf-8c52-451f-88ec-c507cc971c67' User entered '05 Sep 2020 13:01'	System	05 Sep 2020 19:01:10
	System	05 Sep 2020 19:01:10

**US3502045**

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

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 03:33:53

**US3502045**

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

**Form: Medical Attention\_Day(9)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 03:33:53

**US3502045**

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

**Form: Medical Attention\_Day(10)**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	05 Sep 2020 01:55:08
User entered 'Day 10'	System	05 Sep 2020 01:55:08

US3502045

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-07T10:14:44', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '929a0811-438d-450a-be52-58d67205354e' User entered 'No (N)'	System	07 Sep 2020 16:14:50
	System	07 Sep 2020 16:14:50

US3502045

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 07:55:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-07T10:14:47', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '929a0811-438d-450a-be52-58d67205354e' User entered '07 Sep 2020 10:14'	System	07 Sep 2020 16:14:50
	System	07 Sep 2020 16:14:50

**US3502045**

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

**Form: Medical Attention\_Day(10)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '06 Sep 2020 12:00'	System	05 Sep 2020 01:55:08

**US3502045**

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

**Form: Medical Attention\_Day(10)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '07 Sep 2020 11:59'	System	05 Sep 2020 01:55:08



**US3502045**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Laurel Ware (b) (4)	08 Sep 2020 02:17:25

**US3502045**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '05 Sep 2020'	Laurel Ware (b) (4)	08 Sep 2020 02:17:25

**US3502045**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Contact Made (CONTACT MADE)'	Laurel Ware (b) (4)	08 Sep 2020 02:17:25

**US3502045**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered empty.	Laurel Ware (b) (4)	08 Sep 2020 02:17:25

**US3502045**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:55:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Laurel Ware (b) (4)	08 Sep 2020 02:17:32

**US3502045**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:55:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User entered 'I'	System	08 Sep 2020 02:17:32

**US3502045**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	15 Sep 2020 19:06:21

**US3502045**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '11 Sep 2020'	Suzanne Fiorillo (b) (4)	15 Sep 2020 19:06:21



**US3502045**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Contact Made (CONTACT MADE)'	Suzanne Fiorillo (b) (4)	15 Sep 2020 19:06:21

**US3502045**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered empty.	Suzanne Fiorillo (b) (4)	15 Sep 2020 19:06:21

**US3502045**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:55:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	15 Sep 2020 19:06:25

**US3502045**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:55:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 02:19:58
User entered 'I'	System	15 Sep 2020 19:06:25

**US3502045**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:27
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Laurel Ware (b) (4)	22 Sep 2020 16:38:30

**US3502045**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:27
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '18 Sep 2020'	Laurel Ware (b) (4)	22 Sep 2020 16:38:30

**US3502045**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:27
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Contact Made (CONTACT MADE)'	Laurel Ware (b) (4)	22 Sep 2020 16:38:30

**US3502045**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:27
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered empty.	(b) (4) Laurel Ware (b) (4)	22 Sep 2020 16:38:30
	(b) (4)	



**US3502045**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:55:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:27
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Laurel Ware (b) (4)	22 Sep 2020 16:38:41

**US3502045**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:55:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:04:27
User entered 'I'	System	22 Sep 2020 16:38:41

**US3502045**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:55:38**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	25 Sep 2020 13:45:45

**US3502045**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '25 Sep 2020'	Suzanne Fiorillo (b) (4)	25 Sep 2020 13:45:45

**US3502045**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Clinic (Clinic)'	Suzanne Fiorillo (b) (4)	25 Sep 2020 13:45:45

**US3502045**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:55:38**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User entered 'VISIT2'	System	25 Sep 2020 13:45:45

US3502045

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User accepted default value 'Pre-Dose (PREDOSE)'	Suzanne Fiorillo (b) (4) (b) (4)	25 Sep 2020 14:59:47

**US3502045**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	25 Sep 2020 14:59:47



**US3502045**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:55:38**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '25 Sep 2020'	Suzanne Fiorillo (b) (4)	25 Sep 2020 14:59:47

US3502045

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered by System	System	25 Sep 2020 15:00:00
data change (Site from System).		25 Sep 2020 15:00:00
User entered '07:25' reason for change: Data Entry	Suzanne Fiorillo (b) (4)	25 Sep 2020 15:00:00
Error	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	25 Sep 2020 14:59:47
User entered empty.	Suzanne Fiorillo (b) (4)	25 Sep 2020 14:59:47
	(b) (4)	

**US3502045**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User entered '25 Sep 2020 07:25'	System	25 Sep 2020 15:00:00
User entered empty.	System	25 Sep 2020 14:59:47

US3502045

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '97.5' F	Suzanne Fiorillo (b) (4)	25 Sep 2020 14:59:47

**US3502045**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Other (Other)'	Suzanne Fiorillo (b) (4)	25 Sep 2020 14:59:47

**US3502045**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:55:38**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'temporal'	Suzanne Fiorillo (b) (4)	25 Sep 2020 14:59:47

**US3502045**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '81'	Suzanne Fiorillo (b) (4)	25 Sep 2020 14:59:47

**US3502045**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User entered 'bpm'	System	25 Sep 2020 14:59:47



US3502045

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '14'	(b) (4) Suzanne Fiorillo (b) (4)	25 Sep 2020 14:59:47

US3502045

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User entered 'breaths/min'	System	25 Sep 2020 14:59:47

US3502045

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '116'	(b) (4) Suzanne Fiorillo (b) (4)	25 Sep 2020 14:59:47

US3502045

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User entered 'mmHg'	System	25 Sep 2020 14:59:47

**US3502045**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '71'	(b) (4) Suzanne Fiorillo (b) (4)	25 Sep 2020 14:59:47

US3502045

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User entered 'mmHg'	System	25 Sep 2020 14:59:47

US3502045

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User accepted default value 'Post-Dose (POSTDOSE)'	Suzanne Fiorillo (b) (4) (b) (4)	25 Sep 2020 14:59:47

**US3502045**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	25 Sep 2020 14:59:47



US3502045

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '25 Sep 2020'	(b) (4) Suzanne Fiorillo (b) (4)	25 Sep 2020 14:59:47

**US3502045**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '08:33'	(b) (4) Suzanne Fiorillo (b) (4)	25 Sep 2020 14:59:47

**US3502045**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User entered '25 Sep 2020 08:33'	System	25 Sep 2020 14:59:47

US3502045

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '97.2' F	Suzanne Fiorillo (b) (4)	25 Sep 2020 14:59:47

**US3502045**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Other (Other)'	Suzanne Fiorillo (b) (4)	25 Sep 2020 14:59:47

**US3502045**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:55:38**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'temporal'	Suzanne Fiorillo (b) (4)	25 Sep 2020 14:59:47

**US3502045**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '74'	(b) (4) Suzanne Fiorillo (b) (4)	25 Sep 2020 14:59:47

**US3502045**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User entered 'bpm'	System	25 Sep 2020 14:59:47



US3502045

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '16'	(b) (4) Suzanne Fiorillo (b) (4)	25 Sep 2020 14:59:47

US3502045

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User entered 'breaths/min'	System	25 Sep 2020 14:59:47

US3502045

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '114'	Suzanne Fiorillo (b) (4)	25 Sep 2020 14:59:47

**US3502045**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User entered 'mmHg'	System	25 Sep 2020 14:59:47

**US3502045**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '73'	(b) (4) Suzanne Fiorillo (b) (4)	25 Sep 2020 14:59:47

US3502045

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User entered 'mmHg'	System	25 Sep 2020 14:59:47

**US3502045**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:55:38**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	25 Sep 2020 13:46:12

US3502045

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:55:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '25 Sep 2020'	Suzanne Fiorillo (b) (4)	25 Sep 2020 13:46:12



US3502045

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	25 Sep 2020 14:06:30

US3502045

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered empty.	(b) (4) Suzanne Fiorillo (b) (4)	25 Sep 2020 14:06:30

US3502045

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered empty.	Suzanne Fiorillo (b) (4)	25 Sep 2020 14:06:30

**US3502045**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:55:38**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User entered 'MRNA-1273 OR PLACEBO'	System	25 Sep 2020 14:06:30

US3502045

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '25 Sep 2020'	Suzanne Fiorillo (b) (4)	25 Sep 2020 14:06:30

**US3502045**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:55:38**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '08:03'	Suzanne Fiorillo (b) (4)	25 Sep 2020 14:06:30

**US3502045**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:55:38**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User entered '25 Sep 2020 08:03'	System	25 Sep 2020 14:06:30

US3502045

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Left Arm (LEFT ARM)'	Suzanne Fiorillo (b) (4)	25 Sep 2020 14:06:30



US3502045

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User entered 'ONCE'	System	25 Sep 2020 14:06:30

US3502045

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User entered 'INTRAMUSCULAR'	System	25 Sep 2020 14:06:30

US3502045

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	25 Sep 2020 14:53:54

**US3502045**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:55:38**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '25 Sep 2020'	Suzanne Fiorillo (b) (4)	25 Sep 2020 14:53:54

**US3502045**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:55:38**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '07:47'	Suzanne Fiorillo (b) (4)	25 Sep 2020 14:53:54

**US3502045**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:55:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User entered '25 Sep 2020 07:47'	System	25 Sep 2020 14:53:54

**US3502045**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 07:55:38**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '25 Sep 2020'	Suzanne Fiorillo (b) (4)	25 Sep 2020 14:54:11

**US3502045**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Suzanne Fiorillo (b) (4) (b) (4)	25 Sep 2020 14:54:11



**US3502045**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	(b) (4) Suzanne Fiorillo (b) (4)	25 Sep 2020 14:54:11

**US3502045**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 07:55:38**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '07:53'	(b) (4) Suzanne Fiorillo (b) (4)	25 Sep 2020 14:54:11

**US3502045**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User entered '25 Sep 2020 07:53'	System	25 Sep 2020 14:54:11

**US3502045**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Suzanne Fiorillo (b) (4) (b) (4)	25 Sep 2020 14:54:11

**US3502045**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'No (N)'	Suzanne Fiorillo (b) (4)	25 Sep 2020 14:54:11

**US3502045**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 07:55:38**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered empty.	(b) (4) Suzanne Fiorillo (b) (4)	25 Sep 2020 14:54:11

**US3502045**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User entered empty.	System	25 Sep 2020 14:54:11

US3502045

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	(b) (4) Suzanne Fiorillo (b) (4)	25 Sep 2020 14:54:18



**US3502045**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:55:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User entered '1'	System	25 Sep 2020 14:54:18

US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	25 Sep 2020 14:06:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 14:06:30

US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-25T08:24:02', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '9ddecf52-4b06-4e49-b7e1-9220636a4ddb' User entered 'Yes (Y)'	System	25 Sep 2020 14:24:18
	System	25 Sep 2020 14:24:18

US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-25T08:24:07', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '9ddecf52-4b06-4e49-b7e1-9220636a4ddb' User entered '97.2'	System	25 Sep 2020 14:24:18
	System	25 Sep 2020 14:24:18

US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-25T08:24:11', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '9ddecf52-4b06-4e49-b7e1-9220636a4ddb' User entered 'No (N)'	System	25 Sep 2020 14:24:18
	System	25 Sep 2020 14:24:18

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-25T08:24:15', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '9ddecf52-4b06-4e49-b7e1-9220636a4ddb' User entered '25 Sep 2020 08:24'	System	25 Sep 2020 14:24:18
	System	25 Sep 2020 14:24:18

US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '25 Sep 2020 08:23'	System	25 Sep 2020 14:06:30

US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '25 Sep 2020 10:53'	System	25 Sep 2020 14:06:30



US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	25 Sep 2020 14:06:30
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 14:06:30

US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-25T16:48:41', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '4626a4ce-1f72-45be-a248-ce42bda877cf' User entered 'Yes (Y)'	System	25 Sep 2020 22:49:45
	System	25 Sep 2020 22:49:45

US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-25T16:49:35', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '4626a4ce-1f72-45be-a248-ce42bda877cf' User entered '97.7'	System	25 Sep 2020 22:49:45
	System	25 Sep 2020 22:49:45

US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-25T16:49:38', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '4626a4ce-1f72-45be-a248-ce42bda877cf' User entered 'No (N)'	System	25 Sep 2020 22:49:45
	System	25 Sep 2020 22:49:45

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-25T16:49:42', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '4626a4ce-1f72-45be-a248-ce42bda877cf' User entered '25 Sep 2020 16:49'	System	25 Sep 2020 22:49:45
	System	25 Sep 2020 22:49:45

US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '25 Sep 2020 11:48'	System	25 Sep 2020 14:06:30

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 14:06:30

US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	25 Sep 2020 14:06:30
User entered 'Day 2'	System	25 Sep 2020 14:06:30



US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-26T18:46:03', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '60a4a5cf-d183-44ac-8b6d-29d3705ca768' User entered 'Yes (Y)'	System	27 Sep 2020 00:46:43
	System	27 Sep 2020 00:46:43

US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-26T18:46:34', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '60a4a5cf-d183-44ac-8b6d-29d3705ca768' User entered '98.2'	System	27 Sep 2020 00:46:43
	System	27 Sep 2020 00:46:43

US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-26T18:46:37', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '60a4a5cf-d183-44ac-8b6d-29d3705ca768'	System	27 Sep 2020 00:46:43
User entered 'No (N)'	System	27 Sep 2020 00:46:43

**US3502045**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 07:55:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-26T18:46:41', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '60a4a5cf-d183-44ac-8b6d-29d3705ca768'	System	27 Sep 2020 00:46:43
User entered '26 Sep 2020 18:46'	System	27 Sep 2020 00:46:43

US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:55:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 14:06:30

**US3502045**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 14:06:30

US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	25 Sep 2020 14:06:30
User entered 'Day 3'	System	25 Sep 2020 14:06:30

US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:55:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-27T17:34:48', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'c9272794-e8a7-4335-8216-04d969477c57'	System	27 Sep 2020 23:35:01
User entered 'Yes (Y)'	System	27 Sep 2020 23:35:01



US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-27T17:34:53', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'c9272794-e8a7-4335-8216-04d969477c57' User entered '98.2'	System	27 Sep 2020 23:35:01
	System	27 Sep 2020 23:35:01

US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-27T17:34:56', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'c9272794-e8a7-4335-8216-04d969477c57'	System	27 Sep 2020 23:35:01
User entered 'No (N)'	System	27 Sep 2020 23:35:01

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-27T17:35:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'c9272794-e8a7-4335-8216-04d969477c57'	System	27 Sep 2020 23:35:01
User entered '27 Sep 2020 17:35'	System	27 Sep 2020 23:35:01

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 14:06:30

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 14:06:30

US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	25 Sep 2020 14:06:30
User entered 'Day 4'	System	25 Sep 2020 14:06:30

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 07:55:38**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-28T15:47:09', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '5d727459-7c99-4e7f-91e0-21b7b2f54952'	System	28 Sep 2020 21:47:25
User entered 'Yes (Y)'	System	28 Sep 2020 21:47:25

US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-28T15:47:15', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '5d727459-7c99-4e7f-91e0-21b7b2f54952' User entered '97.3'	System	28 Sep 2020 21:47:25
	System	28 Sep 2020 21:47:25



US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-28T15:47:20', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '5d727459-7c99-4e7f-91e0-21b7b2f54952'	System	28 Sep 2020 21:47:25
User entered 'No (N)'	System	28 Sep 2020 21:47:25

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-28T15:47:23', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '5d727459-7c99-4e7f-91e0-21b7b2f54952' User entered '28 Sep 2020 15:47'	System	28 Sep 2020 21:47:25
	System	28 Sep 2020 21:47:25

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 14:06:30

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 14:06:30

US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	25 Sep 2020 14:06:30
User entered 'Day 5'	System	25 Sep 2020 14:06:30

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 07:55:38**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-29T19:21:29', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '398be3bc-ebf2-41b8-9500-b99f71e06fa5' User entered 'Yes (Y)'	System	30 Sep 2020 01:21:45
	System	30 Sep 2020 01:21:45

US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-29T19:21:35', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '398be3bc-ebf2-41b8-9500-b99f71e06fa5' User entered '98.6'	System	30 Sep 2020 01:21:45
	System	30 Sep 2020 01:21:45

US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-29T19:21:40', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '398be3bc-ebf2-41b8-9500-b99f71e06fa5'	System	30 Sep 2020 01:21:45
User entered 'No (N)'	System	30 Sep 2020 01:21:45



**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-29T19:21:43', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '398be3bc-ebf2-41b8-9500-b99f71e06fa5' User entered '29 Sep 2020 19:21'	System	30 Sep 2020 01:21:45
	System	30 Sep 2020 01:21:45

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 14:06:30

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 14:06:30

US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	25 Sep 2020 14:06:30
User entered 'Day 6'	System	25 Sep 2020 14:06:30

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 07:55:38**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-30T16:47:37', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '472130a7-c14a-4b66-a252-7de1c93266f6' User entered 'Yes (Y)'	System	30 Sep 2020 22:48:41
	System	30 Sep 2020 22:48:41

US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-30T16:48:23', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '472130a7-c14a-4b66-a252-7de1c93266f6' User entered '98.1'	System	30 Sep 2020 22:48:41
	System	30 Sep 2020 22:48:41

US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-30T16:48:34', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '472130a7-c14a-4b66-a252-7de1c93266f6' User entered 'No (N)'	System	30 Sep 2020 22:48:41
	System	30 Sep 2020 22:48:41

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-30T16:48:38', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '472130a7-c14a-4b66-a252-7de1c93266f6' User entered '30 Sep 2020 16:48'	System	30 Sep 2020 22:48:41
	System	30 Sep 2020 22:48:41



**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 14:06:30

US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 14:06:30

US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	25 Sep 2020 14:06:30
User entered 'Day 7'	System	25 Sep 2020 14:06:30

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 07:55:38**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-10-01T21:16:39', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'fa91b938-7c38-4c88-b196-cef8a33813dd' User entered 'Yes (Y)'	System	02 Oct 2020 03:17:28
	System	02 Oct 2020 03:17:28

US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:55:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-10-01T21:17:15', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'fa91b938-7c38-4c88-b196-cef8a33813dd' User entered '97.4'	System	02 Oct 2020 03:17:28
	System	02 Oct 2020 03:17:28

US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-10-01T21:17:21', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'fa91b938-7c38-4c88-b196-cef8a33813dd'	System	02 Oct 2020 03:17:28
User entered 'No (N)'	System	02 Oct 2020 03:17:28

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-10-01T21:17:24', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'fa91b938-7c38-4c88-b196-cef8a33813dd' User entered '01 Oct 2020 21:17'	System	02 Oct 2020 03:17:28
	System	02 Oct 2020 03:17:28

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 14:06:30



US3502045

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:55:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 14:06:30

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	25 Sep 2020 14:06:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 14:06:30

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-25T08:24:24', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '6a698d48-9d90-4ade-9c78-416d2635908a' User entered 'None (1)'	System	25 Sep 2020 14:25:07
	System	25 Sep 2020 14:25:07

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-25T08:24:37', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '6a698d48-9d90-4ade-9c78-416d2635908a' User entered 'No (N)'	System	25 Sep 2020 14:25:07
	System	25 Sep 2020 14:25:07

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-25T08:24:51', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '6a698d48-9d90-4ade-9c78-416d2635908a' User entered 'No (N)'	System	25 Sep 2020 14:25:07
	System	25 Sep 2020 14:25:07

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-25T08:24:59', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '6a698d48-9d90-4ade-9c78-416d2635908a' User entered 'None (1)'	System	25 Sep 2020 14:25:07
	System	25 Sep 2020 14:25:07

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-25T08:25:03', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '6a698d48-9d90-4ade-9c78-416d2635908a' User entered '25 Sep 2020 08:25'	System	25 Sep 2020 14:25:07
	System	25 Sep 2020 14:25:07

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '25 Sep 2020 08:23'	System	25 Sep 2020 14:06:30



**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '25 Sep 2020 10:53'	System	25 Sep 2020 14:06:30

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	25 Sep 2020 14:06:30
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 14:06:30

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-25T16:49:46', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'd40de69e-ea40-4a97-a98f-5a1cc6f4c589'	System	25 Sep 2020 22:50:07
User entered 'None (1)'	System	25 Sep 2020 22:50:07

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-25T16:49:55', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'd40de69e-ea40-4a97-a98f-5a1cc6f4c589'	System	25 Sep 2020 22:50:07
User entered 'No (N)'	System	25 Sep 2020 22:50:07

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-25T16:49:58', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'd40de69e-ea40-4a97-a98f-5a1cc6f4c589'	System	25 Sep 2020 22:50:07
User entered 'No (N)'	System	25 Sep 2020 22:50:07

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-25T16:50:03', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'd40de69e-ea40-4a97-a98f-5a1cc6f4c589'	System	25 Sep 2020 22:50:07
User entered 'None (1)'	System	25 Sep 2020 22:50:07

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-25T16:50:06', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'd40de69e-ea40-4a97-a98f-5a1cc6f4c589'	System	25 Sep 2020 22:50:07
User entered '25 Sep 2020 16:50'	System	25 Sep 2020 22:50:07

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '25 Sep 2020 11:48'	System	25 Sep 2020 14:06:30



**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 14:06:30

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	25 Sep 2020 14:06:30
User entered 'Day 2'	System	25 Sep 2020 14:06:30

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-26T18:46:46', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '48a75db8-59bf-4ccb-ae6f-270599e386f5'	System	27 Sep 2020 00:47:03
User entered 'None (1)'	System	27 Sep 2020 00:47:03

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-26T18:46:52', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '48a75db8-59bf-4ccb-ae6f-270599e386f5' User entered 'No (N)'	System	27 Sep 2020 00:47:03
	System	27 Sep 2020 00:47:03

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-26T18:46:55', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '48a75db8-59bf-4ccb-ae6f-270599e386f5'	System	27 Sep 2020 00:47:03
User entered 'No (N)'	System	27 Sep 2020 00:47:03

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-26T18:46:58', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '48a75db8-59bf-4ccb-ae6f-270599e386f5'	System	27 Sep 2020 00:47:03
User entered 'None (1)'	System	27 Sep 2020 00:47:03

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-26T18:47:01', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '48a75db8-59bf-4ccb-ae6f-270599e386f5' User entered '26 Sep 2020 18:47'	System	27 Sep 2020 00:47:03
	System	27 Sep 2020 00:47:03

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 14:06:30



**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 14:06:30

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	25 Sep 2020 14:06:30
User entered 'Day 3'	System	25 Sep 2020 14:06:30

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-27T17:35:15', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'fd66fe84-e7d8-485b-b9ce-f78507392ab4'	System	27 Sep 2020 23:35:50
User entered 'None (1)'	System	27 Sep 2020 23:35:50

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-27T17:35:38', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'fd66fe84-e7d8-485b-b9ce-f78507392ab4'	System	27 Sep 2020 23:35:50
User entered 'No (N)'	System	27 Sep 2020 23:35:50

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-27T17:35:41', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'fd66fe84-e7d8-485b-b9ce-f78507392ab4'	System	27 Sep 2020 23:35:50
User entered 'No (N)'	System	27 Sep 2020 23:35:50

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-27T17:35:44', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'fd66fe84-e7d8-485b-b9ce-f78507392ab4'	System	27 Sep 2020 23:35:50
User entered 'None (1)'	System	27 Sep 2020 23:35:50

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-27T17:35:47', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'fd66fe84-e7d8-485b-b9ce-f78507392ab4' User entered '27 Sep 2020 17:35'	System	27 Sep 2020 23:35:50
	System	27 Sep 2020 23:35:50

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 14:06:30



**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 14:06:30

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	25 Sep 2020 14:06:30
User entered 'Day 4'	System	25 Sep 2020 14:06:30

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-28T15:47:28', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'a36ce5ca-47f9-40ee-b971-660dd778d001'	System	28 Sep 2020 21:47:43
User entered 'None (1)'	System	28 Sep 2020 21:47:43

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-28T15:47:31', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'a36ce5ca-47f9-40ee-b971-660dd778d001' User entered 'No (N)'	System	28 Sep 2020 21:47:43
	System	28 Sep 2020 21:47:43

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-28T15:47:33', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'a36ce5ca-47f9-40ee-b971-660dd778d001' User entered 'No (N)'	System	28 Sep 2020 21:47:43
	System	28 Sep 2020 21:47:43

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-28T15:47:36', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'a36ce5ca-47f9-40ee-b971-660dd778d001'	System	28 Sep 2020 21:47:43
User entered 'None (1)'	System	28 Sep 2020 21:47:43

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-28T15:47:39', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'a36ce5ca-47f9-40ee-b971-660dd778d001' User entered '28 Sep 2020 15:47'	System	28 Sep 2020 21:47:43
	System	28 Sep 2020 21:47:43

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 14:06:30



**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 14:06:30

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	25 Sep 2020 14:06:30
User entered 'Day 5'	System	25 Sep 2020 14:06:30

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-29T19:21:57', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '140b8e01-29cb-467a-b50e-25aee1afecdd'	System	30 Sep 2020 01:22:21
User entered 'Does not interfere with activity (2)'	System	30 Sep 2020 01:22:21

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-29T19:22:01', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '140b8e01-29cb-467a-b50e-25aee1afecdd' User entered 'No (N)'	System	30 Sep 2020 01:22:21
	System	30 Sep 2020 01:22:21

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-29T19:22:08', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '140b8e01-29cb-467a-b50e-25aee1afecdd' User entered 'No (N)'	System	30 Sep 2020 01:22:21
	System	30 Sep 2020 01:22:21

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-29T19:22:12', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '140b8e01-29cb-467a-b50e-25aee1afecdd' User entered 'None (1)'	System	30 Sep 2020 01:22:21
	System	30 Sep 2020 01:22:21

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-29T19:22:15', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '140b8e01-29cb-467a-b50e-25aee1afecdd' User entered '29 Sep 2020 19:22'	System	30 Sep 2020 01:22:21
	System	30 Sep 2020 01:22:21

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 14:06:30



**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 14:06:30

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	25 Sep 2020 14:06:30
User entered 'Day 6'	System	25 Sep 2020 14:06:30

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-30T16:48:46', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '1284bca5-e018-4988-af61-ba8c17bd1090'	System	30 Sep 2020 22:49:14
User entered 'None (1)'	System	30 Sep 2020 22:49:14

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-30T16:48:56', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '1284bca5-e018-4988-af61-ba8c17bd1090' User entered 'No (N)'	System	30 Sep 2020 22:49:14
	System	30 Sep 2020 22:49:14

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-30T16:49:04', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '1284bca5-e018-4988-af61-ba8c17bd1090' User entered 'No (N)'	System	30 Sep 2020 22:49:14
	System	30 Sep 2020 22:49:14

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-30T16:49:10', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '1284bca5-e018-4988-af61-ba8c17bd1090'	System	30 Sep 2020 22:49:14
User entered 'None (1)'	System	30 Sep 2020 22:49:14

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-30T16:49:13', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '1284bca5-e018-4988-af61-ba8c17bd1090' User entered '30 Sep 2020 16:49'	System	30 Sep 2020 22:49:14
	System	30 Sep 2020 22:49:14

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 14:06:30



**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 14:06:30

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	25 Sep 2020 14:06:30
User entered 'Day 7'	System	25 Sep 2020 14:06:30

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-10-01T21:17:28', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '297c34ac-33b1-47ef-a612-15816a35fc2d'	System	02 Oct 2020 03:17:41
User entered 'None (1)'	System	02 Oct 2020 03:17:41

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:55:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-10-01T21:17:31', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '297c34ac-33b1-47ef-a612-15816a35fc2d' User entered 'No (N)'	System	02 Oct 2020 03:17:41
	System	02 Oct 2020 03:17:41

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-10-01T21:17:34', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '297c34ac-33b1-47ef-a612-15816a35fc2d' User entered 'No (N)'	System	02 Oct 2020 03:17:41
	System	02 Oct 2020 03:17:41

US3502045

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-10-01T21:17:36', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '297c34ac-33b1-47ef-a612-15816a35fc2d' User entered 'None (1)'	System	02 Oct 2020 03:17:41
	System	02 Oct 2020 03:17:41

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-10-01T21:17:40', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '297c34ac-33b1-47ef-a612-15816a35fc2d' User entered '01 Oct 2020 21:17'	System	02 Oct 2020 03:17:41
	System	02 Oct 2020 03:17:41

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 14:06:30



**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 14:06:30

US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	25 Sep 2020 14:06:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Sep 2020 14:06:30

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:55:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-25T08:25:11', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '81d7f771-27cd-4b16-af1c-958aacb9e863' User entered 'None (0)'	System	25 Sep 2020 14:25:43
	System	25 Sep 2020 14:25:43

US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-25T08:25:15', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '81d7f771-27cd-4b16-af1c-958aacb9e863' User entered 'None (0)'	System	25 Sep 2020 14:25:43
	System	25 Sep 2020 14:25:43

US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-25T08:25:20', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '81d7f771-27cd-4b16-af1c-958aacb9e863' User entered 'None (0)'	System	25 Sep 2020 14:25:43
	System	25 Sep 2020 14:25:43

US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-25T08:25:22', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '81d7f771-27cd-4b16-af1c-958aacb9e863' User entered 'None (0)'	System	25 Sep 2020 14:25:43
	System	25 Sep 2020 14:25:43

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:55:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-25T08:25:25', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '81d7f771-27cd-4b16-af1c-958aacb9e863' User entered 'None (0)'	System	25 Sep 2020 14:25:43
	System	25 Sep 2020 14:25:43

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:55:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-25T08:25:30', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '81d7f771-27cd-4b16-af1c-958aacb9e863' User entered 'None (0)'	System	25 Sep 2020 14:25:43
	System	25 Sep 2020 14:25:43



US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-25T08:25:34', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '81d7f771-27cd-4b16-af1c-958aacb9e863' User entered 'No (N)'	System	25 Sep 2020 14:25:43
	System	25 Sep 2020 14:25:43

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-25T08:25:38', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '81d7f771-27cd-4b16-af1c-958aacb9e863' User entered '25 Sep 2020 08:25'	System	25 Sep 2020 14:25:43
	System	25 Sep 2020 14:25:43

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '25 Sep 2020 08:23'	System	25 Sep 2020 14:06:30

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '25 Sep 2020 10:53'	System	25 Sep 2020 14:06:30

US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	25 Sep 2020 14:06:30
User entered 'Day 1, after vaccination (at home)'	System	25 Sep 2020 14:06:30

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:55:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-25T16:50:11', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '0e60a529-c104-44ed-98d0-d6853582cf5d' User entered 'None (0)'	System	25 Sep 2020 22:50:40
	System	25 Sep 2020 22:50:40

US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-25T16:50:14', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '0e60a529-c104-44ed-98d0-d6853582cf5d' User entered 'None (0)'	System	25 Sep 2020 22:50:40
	System	25 Sep 2020 22:50:40

US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-25T16:50:16', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '0e60a529-c104-44ed-98d0-d6853582cf5d' User entered 'None (0)'	System	25 Sep 2020 22:50:40
	System	25 Sep 2020 22:50:40



**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:55:38**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-25T16:50:23', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '0e60a529-c104-44ed-98d0-d6853582cf5d' User entered 'None (0)'	System	25 Sep 2020 22:50:40
	System	25 Sep 2020 22:50:40

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:55:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-25T16:50:25', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '0e60a529-c104-44ed-98d0-d6853582cf5d' User entered 'None (0)'	System	25 Sep 2020 22:50:40
	System	25 Sep 2020 22:50:40

US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-25T16:50:28', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '0e60a529-c104-44ed-98d0-d6853582cf5d' User entered 'None (0)'	System	25 Sep 2020 22:50:40
	System	25 Sep 2020 22:50:40

US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-25T16:50:31', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '0e60a529-c104-44ed-98d0-d6853582cf5d' User entered 'No (N)'	System	25 Sep 2020 22:50:40
	System	25 Sep 2020 22:50:40

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-25T16:50:35', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '0e60a529-c104-44ed-98d0-d6853582cf5d' User entered '25 Sep 2020 16:50'	System	25 Sep 2020 22:50:40
	System	25 Sep 2020 22:50:40

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '25 Sep 2020 11:48'	System	25 Sep 2020 14:06:30

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '26 Sep 2020 11:59'	System	25 Sep 2020 14:06:30

**US3502045**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	25 Sep 2020 14:06:30
User entered 'Day 2'	System	25 Sep 2020 14:06:30



**US3502045**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 07:55:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-26T18:47:06', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'f5946d6b-5758-437e-a398-6f5e1cf4b3d8' User entered 'None (0)'	System	27 Sep 2020 00:47:28
	System	27 Sep 2020 00:47:28

**US3502045**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 07:55:38**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-26T18:47:09', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'f5946d6b-5758-437e-a398-6f5e1cf4b3d8'	System	27 Sep 2020 00:47:28
User entered 'None (0)'	System	27 Sep 2020 00:47:28

US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:55:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-26T18:47:11', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'f5946d6b-5758-437e-a398-6f5e1cf4b3d8' User entered 'None (0)'	System	27 Sep 2020 00:47:28
	System	27 Sep 2020 00:47:28

US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:55:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-26T18:47:14', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'f5946d6b-5758-437e-a398-6f5e1cf4b3d8' User entered 'None (0)'	System	27 Sep 2020 00:47:28
	System	27 Sep 2020 00:47:28

**US3502045**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 07:55:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-26T18:47:16', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'f5946d6b-5758-437e-a398-6f5e1cf4b3d8' User entered 'None (0)'	System	27 Sep 2020 00:47:28
	System	27 Sep 2020 00:47:28

**US3502045**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 07:55:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-26T18:47:19', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'f5946d6b-5758-437e-a398-6f5e1cf4b3d8' User entered 'None (0)'	System	27 Sep 2020 00:47:28
	System	27 Sep 2020 00:47:28

US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-26T18:47:22', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'f5946d6b-5758-437e-a398-6f5e1cf4b3d8' User entered 'No (N)'	System	27 Sep 2020 00:47:28
	System	27 Sep 2020 00:47:28

**US3502045**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 07:55:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-26T18:47:25', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'f5946d6b-5758-437e-a398-6f5e1cf4b3d8' User entered '26 Sep 2020 18:47'	System	27 Sep 2020 00:47:28
	System	27 Sep 2020 00:47:28



**US3502045**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '26 Sep 2020 12:00'	System	25 Sep 2020 14:06:30

**US3502045**

**Folder: Diary Dose 2 (1)**

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

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '27 Sep 2020 11:59'	System	25 Sep 2020 14:06:30

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	25 Sep 2020 14:06:30
User entered 'Day 3'	System	25 Sep 2020 14:06:30

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:55:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-27T17:35:52', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'fb219882-4a66-4294-9a8f-8a1f1176843a' User entered 'None (0)'	System	27 Sep 2020 23:36:11
	System	27 Sep 2020 23:36:11

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:55:38**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-27T17:35:54', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'fb219882-4a66-4294-9a8f-8a1f1176843a' User entered 'None (0)'	System	27 Sep 2020 23:36:11
	System	27 Sep 2020 23:36:11

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:55:38**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-27T17:35:56', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'fb219882-4a66-4294-9a8f-8a1f1176843a' User entered 'None (0)'	System	27 Sep 2020 23:36:11
	System	27 Sep 2020 23:36:11

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:55:38**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-27T17:35:59', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'fb219882-4a66-4294-9a8f-8a1f1176843a' User entered 'None (0)'	System	27 Sep 2020 23:36:11
	System	27 Sep 2020 23:36:11

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:55:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-27T17:36:01', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'fb219882-4a66-4294-9a8f-8a1f1176843a' User entered 'None (0)'	System	27 Sep 2020 23:36:11
	System	27 Sep 2020 23:36:11



**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:55:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-27T17:36:03', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'fb219882-4a66-4294-9a8f-8a1f1176843a' User entered 'None (0)'	System	27 Sep 2020 23:36:11
	System	27 Sep 2020 23:36:11

US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-27T17:36:05', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'fb219882-4a66-4294-9a8f-8a1f1176843a' User entered 'No (N)'	System	27 Sep 2020 23:36:11
	System	27 Sep 2020 23:36:11

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-27T17:36:08', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'fb219882-4a66-4294-9a8f-8a1f1176843a' User entered '27 Sep 2020 17:36'	System	27 Sep 2020 23:36:11
	System	27 Sep 2020 23:36:11

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '27 Sep 2020 12:00'	System	25 Sep 2020 14:06:30

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '28 Sep 2020 11:59'	System	25 Sep 2020 14:06:30

US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	25 Sep 2020 14:06:30
User entered 'Day 4'	System	25 Sep 2020 14:06:30

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:55:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-28T15:47:47', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '277ed32a-aa8e-4812-888a-17b5fc9c81e7'	System	28 Sep 2020 21:48:11
User entered 'No interference with activity (1)'	System	28 Sep 2020 21:48:11

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:55:38**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-28T15:47:50', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '277ed32a-aa8e-4812-888a-17b5fc9c81e7' User entered 'None (0)'	System	28 Sep 2020 21:48:11
	System	28 Sep 2020 21:48:11



US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:55:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-28T15:47:53', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '277ed32a-aa8e-4812-888a-17b5fc9c81e7' User entered 'None (0)'	System	28 Sep 2020 21:48:11
	System	28 Sep 2020 21:48:11

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:55:38**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-28T15:47:55', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '277ed32a-aa8e-4812-888a-17b5fc9c81e7' User entered 'None (0)'	System	28 Sep 2020 21:48:11
	System	28 Sep 2020 21:48:11

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:55:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-28T15:47:58', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '277ed32a-aa8e-4812-888a-17b5fc9c81e7' User entered 'None (0)'	System	28 Sep 2020 21:48:11
	System	28 Sep 2020 21:48:11

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:55:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-28T15:48:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '277ed32a-aa8e-4812-888a-17b5fc9c81e7' User entered 'None (0)'	System	28 Sep 2020 21:48:11
	System	28 Sep 2020 21:48:11

US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-28T15:48:03', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '277ed32a-aa8e-4812-888a-17b5fc9c81e7'	System	28 Sep 2020 21:48:11
User entered 'No (N)'	System	28 Sep 2020 21:48:11

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-28T15:48:05', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '277ed32a-aa8e-4812-888a-17b5fc9c81e7' User entered '28 Sep 2020 15:48'	System	28 Sep 2020 21:48:11
	System	28 Sep 2020 21:48:11

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '28 Sep 2020 12:00'	System	25 Sep 2020 14:06:30

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '29 Sep 2020 11:59'	System	25 Sep 2020 14:06:30



**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	25 Sep 2020 14:06:30
User entered 'Day 5'	System	25 Sep 2020 14:06:30

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:55:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-29T19:22:21', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'cbdd4f31-6fac-4d28-b10a-d805a84014e8'	System	30 Sep 2020 01:22:42
User entered 'No interference with activity (1)'	System	30 Sep 2020 01:22:42

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:55:38**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-29T19:22:23', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'cbdd4f31-6fac-4d28-b10a-d805a84014e8' User entered 'None (0)'	System	30 Sep 2020 01:22:42
	System	30 Sep 2020 01:22:42

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:55:38**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-29T19:22:26', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'cbdd4f31-6fac-4d28-b10a-d805a84014e8' User entered 'None (0)'	System	30 Sep 2020 01:22:42
	System	30 Sep 2020 01:22:42

US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:55:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-29T19:22:28', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'cbdd4f31-6fac-4d28-b10a-d805a84014e8' User entered 'None (0)'	System	30 Sep 2020 01:22:42
	System	30 Sep 2020 01:22:42

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:55:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-29T19:22:31', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'cbdd4f31-6fac-4d28-b10a-d805a84014e8' User entered 'None (0)'	System	30 Sep 2020 01:22:42
	System	30 Sep 2020 01:22:42

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:55:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-29T19:22:33', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'cbdd4f31-6fac-4d28-b10a-d805a84014e8' User entered 'None (0)'	System	30 Sep 2020 01:22:42
	System	30 Sep 2020 01:22:42

US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-29T19:22:36', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'cbdd4f31-6fac-4d28-b10a-d805a84014e8' User entered 'No (N)'	System	30 Sep 2020 01:22:42
	System	30 Sep 2020 01:22:42



**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-29T19:22:39', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'cbdd4f31-6fac-4d28-b10a-d805a84014e8' User entered '29 Sep 2020 19:22'	System	30 Sep 2020 01:22:42
	System	30 Sep 2020 01:22:42

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '29 Sep 2020 12:00'	System	25 Sep 2020 14:06:30

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '30 Sep 2020 11:59'	System	25 Sep 2020 14:06:30

US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:55:38

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	25 Sep 2020 14:06:30
User entered 'Day 6'	System	25 Sep 2020 14:06:30

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:55:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-30T16:49:20', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '730c9352-d815-4c7e-9da2-29cec6264a9d' User entered 'None (0)'	System	30 Sep 2020 22:49:45
	System	30 Sep 2020 22:49:45

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:55:38**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-30T16:49:23', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '730c9352-d815-4c7e-9da2-29cec6264a9d' User entered 'None (0)'	System	30 Sep 2020 22:49:45
	System	30 Sep 2020 22:49:45

US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:55:38

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-30T16:49:26', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '730c9352-d815-4c7e-9da2-29cec6264a9d' User entered 'None (0)'	System	30 Sep 2020 22:49:45
	System	30 Sep 2020 22:49:45

US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:55:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-30T16:49:29', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '730c9352-d815-4c7e-9da2-29cec6264a9d' User entered 'None (0)'	System	30 Sep 2020 22:49:45
	System	30 Sep 2020 22:49:45



US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:55:38

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-30T16:49:31', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '730c9352-d815-4c7e-9da2-29cec6264a9d' User entered 'None (0)'	System	30 Sep 2020 22:49:45
	System	30 Sep 2020 22:49:45

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:55:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-30T16:49:34', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '730c9352-d815-4c7e-9da2-29cec6264a9d' User entered 'None (0)'	System	30 Sep 2020 22:49:45
	System	30 Sep 2020 22:49:45

US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-30T16:49:37', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '730c9352-d815-4c7e-9da2-29cec6264a9d' User entered 'No (N)'	System	30 Sep 2020 22:49:45
	System	30 Sep 2020 22:49:45

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-09-30T16:49:40', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '730c9352-d815-4c7e-9da2-29cec6264a9d' User entered '30 Sep 2020 16:49'	System	30 Sep 2020 22:49:45
	System	30 Sep 2020 22:49:45

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '30 Sep 2020 12:00'	System	25 Sep 2020 14:06:30

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '01 Oct 2020 11:59'	System	25 Sep 2020 14:06:30

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	25 Sep 2020 14:06:30
User entered 'Day 7'	System	25 Sep 2020 14:06:30

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:55:38**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-10-01T21:17:47', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '0a8dc03d-b799-4c94-b6bb-2c51f6e36729' User entered 'None (0)'	System	02 Oct 2020 03:18:07
	System	02 Oct 2020 03:18:07



**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:55:38**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-10-01T21:17:50', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '0a8dc03d-b799-4c94-b6bb-2c51f6e36729' User entered 'None (0)'	System	02 Oct 2020 03:18:07
	System	02 Oct 2020 03:18:07

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:55:38**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-10-01T21:17:52', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '0a8dc03d-b799-4c94-b6bb-2c51f6e36729' User entered 'None (0)'	System	02 Oct 2020 03:18:07
	System	02 Oct 2020 03:18:07

US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:55:38

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-10-01T21:17:54', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '0a8dc03d-b799-4c94-b6bb-2c51f6e36729' User entered 'None (0)'	System	02 Oct 2020 03:18:07
	System	02 Oct 2020 03:18:07

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:55:38**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-10-01T21:17:57', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '0a8dc03d-b799-4c94-b6bb-2c51f6e36729' User entered 'None (0)'	System	02 Oct 2020 03:18:07
	System	02 Oct 2020 03:18:07

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:55:38**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-10-01T21:18:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '0a8dc03d-b799-4c94-b6bb-2c51f6e36729' User entered 'None (0)'	System	02 Oct 2020 03:18:07
	System	02 Oct 2020 03:18:07

US3502045

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:55:38

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 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-10-01T21:18:02', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '0a8dc03d-b799-4c94-b6bb-2c51f6e36729' User entered 'No (N)'	System	02 Oct 2020 03:18:07
	System	02 Oct 2020 03:18:07

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-10-01T21:18:05', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '0a8dc03d-b799-4c94-b6bb-2c51f6e36729' User entered '01 Oct 2020 21:18'	System	02 Oct 2020 03:18:07
	System	02 Oct 2020 03:18:07

**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '01 Oct 2020 12:00'	System	25 Sep 2020 14:06:30



**US3502045**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:55:38**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
User entered '02 Oct 2020 11:59'	System	25 Sep 2020 14:06:30

**US3502045**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
User entered 'Yes (Y)'	Laurel Ware (b) (4)	26 Mar 2021 18:34:16

**US3502045**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
User entered '02 Oct 2020'	Laurel Ware (b) (4)	26 Mar 2021 18:34:16

**US3502045**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
User entered 'Contact Not Made (CONTACT NOT MADE)'	Laurel Ware (b) (4)	26 Mar 2021 18:34:16

US3502045

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
User entered 'ATTEMPTED X3'	(b) (4) Laurel Ware (b) (4) (b) (4)	26 Mar 2021 18:34:16

**US3502045**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:55:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	(b) (4) Patrisha Adkins (b) (4) (b) (4)	19 Oct 2020 19:32:31

**US3502045**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:55:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User entered 'I'	System	19 Oct 2020 19:32:31

**US3502045**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	(b) (4) Patrisha Adkins (b) (4)	19 Oct 2020 19:32:56



**US3502045**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '9 Oct 2020'	(b) (4) Patrisha Adkins (b) (4) (b) (4)	19 Oct 2020 19:32:56

**US3502045**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Patrisha Adkins (b) (4) (b) (4)	19 Oct 2020 19:32:56

US3502045

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered empty.	(b) (4) Patrishia Adkins (b) (4) (b) (4)	19 Oct 2020 19:32:56

**US3502045**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:55:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	(b) (4) Patrisha Adkins (b) (4) (b) (4)	19 Oct 2020 19:33:03

**US3502045**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:55:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User entered 'I'	System	19 Oct 2020 19:33:03

**US3502045**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	(b) (4) Patrisha Adkins (b) (4)	19 Oct 2020 19:33:27

**US3502045**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '16 Oct 2020'	(b) (4) Patrisha Adkins (b) (4) (b) (4)	19 Oct 2020 19:33:27

**US3502045**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Patrisha Adkins (b) (4) (b) (4)	19 Oct 2020 19:33:27



US3502045

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered empty.	(b) (4) Patrishia Adkins (b) (4) (b) (4)	19 Oct 2020 19:33:27

**US3502045**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:55:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Patrishia Adkins (b) (4)	19 Oct 2020 19:33:35

**US3502045**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:55:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User entered 'I'	System	19 Oct 2020 19:33:35

**US3502045**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:55:38**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	(b) (4) Suzanne Fiorillo (b) (4)	23 Oct 2020 14:54:36

**US3502045**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '23 Oct 2020'	Suzanne Fiorillo (b) (4)	23 Oct 2020 14:54:36

**US3502045**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Clinic (Clinic)'	Suzanne Fiorillo (b) (4)	23 Oct 2020 14:54:36

**US3502045**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:55:38**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User entered 'VISIT3'	System	23 Oct 2020 14:54:36

**US3502045**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	23 Oct 2020 14:57:25



US3502045

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '23 Oct 2020'	Suzanne Fiorillo (b) (4)	23 Oct 2020 14:57:25

**US3502045**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '07:22'	(b) (4) Suzanne Fiorillo (b) (4)	23 Oct 2020 14:57:25

**US3502045**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User entered '23 Oct 2020 07:22'	System	23 Oct 2020 14:57:25

US3502045

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
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)	27 Oct 2020 05:14:48
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)	23 Oct 2020 14:57:34
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	23 Oct 2020 14:57:25
User entered '35.9' C	Suzanne Fiorillo (b) (4) (b) (4)	23 Oct 2020 14:57:25

**US3502045**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Other (Other)'	Suzanne Fiorillo (b) (4)	23 Oct 2020 14:57:25

**US3502045**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'temporal'	Suzanne Fiorillo (b) (4)	23 Oct 2020 14:57:25

**US3502045**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '65'	Suzanne Fiorillo (b) (4)	23 Oct 2020 14:57:25

**US3502045**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User entered 'bpm'	System	23 Oct 2020 14:57:25



US3502045

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '14'	Suzanne Fiorillo (b) (4)	23 Oct 2020 14:57:25

**US3502045**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User entered 'breaths/min'	System	23 Oct 2020 14:57:25

**US3502045**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '130'	(b) (4) Suzanne Fiorillo (b) (4)	23 Oct 2020 14:57:25

**US3502045**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User entered 'mmHg'	System	23 Oct 2020 14:57:25

US3502045

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '71'	Suzanne Fiorillo (b) (4)	23 Oct 2020 14:57:25

**US3502045**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User entered 'mmHg'	System	23 Oct 2020 14:57:25

**US3502045**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51

**US3502045**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51



**US3502045**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:55:38**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	30 Dec 2020 21:50:17
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4) (b) (4)	23 Oct 2020 14:54:46

**US3502045**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:55:38**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 21:50:17
User entered '23 Oct 2020'	Suzanne Fiorillo (b) (4)	23 Oct 2020 14:54:46

**US3502045**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:55:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	23 Oct 2020 14:58:01

US3502045

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '23 Oct 2020'	Suzanne Fiorillo (b) (4)	23 Oct 2020 14:58:01

**US3502045**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:55:38**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '07:41'	Suzanne Fiorillo (b) (4)	23 Oct 2020 14:58:01

**US3502045**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:55:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User entered '23 Oct 2020 07:41'	System	23 Oct 2020 14:58:01

US3502045

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	(b) (4) Suzanne Fiorillo (b) (4)	23 Oct 2020 14:58:07

**US3502045**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:55:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User entered 'I'	System	23 Oct 2020 14:58:07



**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	28 Aug 2020 14:23:22
User entered 'Day 64'	System	28 Aug 2020 14:23:22

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-10-28T21:29:49', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '394d9680-7fed-4720-97a6-5142be9aa9f4'	System	29 Oct 2020 03:30:05
User entered 'No (N)'	System	29 Oct 2020 03:30:05

US3502045

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:55:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-10-28T21:29:53', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '394d9680-7fed-4720-97a6-5142be9aa9f4'	System	29 Oct 2020 03:30:05
User entered 'No (N)'	System	29 Oct 2020 03:30:05

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-10-28T21:30:01', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '394d9680-7fed-4720-97a6-5142be9aa9f4' User entered '28 Oct 2020 21:30:01'	System	29 Oct 2020 03:30:05
	System	29 Oct 2020 03:30:05

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	28 Aug 2020 14:23:22
User entered '28 Oct 2020 00:01'	System	28 Aug 2020 14:23:22

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	28 Aug 2020 14:23:22
User entered '01 Nov 2020 23:59'	System	28 Aug 2020 14:23:22

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	28 Aug 2020 14:23:22
User entered 'Day 71'	System	28 Aug 2020 14:23:22

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-11-05T20:06:20', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '94e449e8-0b73-4eff-aa6b-6972e401e800'	System	06 Nov 2020 03:06:33
User entered 'No (N)'	System	06 Nov 2020 03:06:33



**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-11-05T20:06:23', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '94e449e8-0b73-4eff-aa6b-6972e401e800'	System	06 Nov 2020 03:06:33
User entered 'No (N)'	System	06 Nov 2020 03:06:33

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-11-05T20:06:29', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '94e449e8-0b73-4eff-aa6b-6972e401e800'	System	06 Nov 2020 03:06:33
User entered '05 Nov 2020 20:06:29'	System	06 Nov 2020 03:06:33

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	28 Aug 2020 14:23:22
User entered '04 Nov 2020 00:01'	System	28 Aug 2020 14:23:22

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	28 Aug 2020 14:23:22
User entered '08 Nov 2020 23:59'	System	28 Aug 2020 14:23:22

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	28 Aug 2020 14:23:22
User entered 'Day 78'	System	28 Aug 2020 14:23:22

**US3502045**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-11-14T21:01:33', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'af638137-9382-4b5e-be66-934310f9cf86'	System	15 Nov 2020 04:02:07
User entered 'Yes (Y)'	System	15 Nov 2020 04:02:07

**US3502045**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-11-14T21:01:37', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'af638137-9382-4b5e-be66-934310f9cf86'	System	15 Nov 2020 04:02:07
User entered 'No (N)'	System	15 Nov 2020 04:02:07

**US3502045**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[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)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-11-14T21:01:44', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'af638137-9382-4b5e-be66-934310f9cf86'	System	15 Nov 2020 04:02:07
User entered 'No (N)'	System	15 Nov 2020 04:02:07



**US3502045**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[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)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-11-14T21:01:48', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'af638137-9382-4b5e-be66-934310f9cf86'	System	15 Nov 2020 04:02:07
User entered 'No (N)'	System	15 Nov 2020 04:02:07

**US3502045**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-11-14T21:02:01', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'af638137-9382-4b5e-be66-934310f9cf86' User entered '14 Nov 2020 21:02:01'	System	15 Nov 2020 04:02:07
	System	15 Nov 2020 04:02:07

**US3502045**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	28 Aug 2020 14:23:22
User entered '11 Nov 2020 00:01'	System	28 Aug 2020 14:23:22

**US3502045**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 16:32:14
Data entry locked.	System	28 Aug 2020 14:23:22
User entered '15 Nov 2020 23:59'	System	28 Aug 2020 14:23:22

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-11-26T22:36:28', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '47f2c1e4-dc35-43eb-a97a-e5897e3f81f9' User entered 'No (N)'	System	27 Nov 2020 05:36:40
	System	27 Nov 2020 05:36:40

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Have you been exposed to someone with 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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-11-26T22:36:32', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '47f2c1e4-dc35-43eb-a97a-e5897e3f81f9' User entered 'No (N)'	System	27 Nov 2020 05:36:40

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-11-26T22:36:37', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '47f2c1e4-dc35-43eb-a97a-e5897e3f81f9' User entered '26 Nov 2020 22:36:37'	System	27 Nov 2020 05:36:40
	System	27 Nov 2020 05:36:40



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-12-01T20:50:18', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'ea297e44-d8f8-4c4f-9588-be2569dc5a2d' User entered 'No (N)'	System	02 Dec 2020 03:50:28
	System	02 Dec 2020 03:50:28

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Have you been exposed to someone with 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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-12-01T20:50:21', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'ea297e44-d8f8-4c4f-9588-be2569dc5a2d'	System	02 Dec 2020 03:50:28
User entered 'No (N)'	System	02 Dec 2020 03:50:28

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-12-01T20:50:26', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'ea297e44-d8f8-4c4f-9588-be2569dc5a2d' User entered '01 Dec 2020 20:50:26'	System	02 Dec 2020 03:50:28
	System	02 Dec 2020 03:50:28

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 19:38:32



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-12-06T14:36:59', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '7796153c-eba4-4ae7-aec8-4190cdd4bbed' User entered 'No (N)'	System	06 Dec 2020 21:37:10
	System	06 Dec 2020 21:37:10

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Have you been exposed to someone with 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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-12-06T14:37:03', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '7796153c-eba4-4ae7-aec8-4190cdd4bbed' User entered 'No (N)'	System	06 Dec 2020 21:37:10

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-12-06T14:37:06', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '7796153c-eba4-4ae7-aec8-4190cdd4bbed' User entered '06 Dec 2020 14:37:06'	System	06 Dec 2020 21:37:10
	System	06 Dec 2020 21:37:10

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-12-13T21:27:17', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '559ac925-ebac-478b-84c4-67c72a400e8f' User entered 'Yes (Y)'	System	14 Dec 2020 04:33:38
	System	14 Dec 2020 04:33:38



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Have you been exposed to someone with 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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-12-13T21:27:22', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '559ac925-ebac-478b-84c4-67c72a400e8f' User entered 'No (N)'	System	14 Dec 2020 04:33:38
	System	14 Dec 2020 04:33:38

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-12-13T21:33:26', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '559ac925-ebac-478b-84c4-67c72a400e8f' User entered 'No (N)'	System	14 Dec 2020 04:33:38
	System	14 Dec 2020 04:33:38

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-12-13T21:30:40', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '559ac925-ebac-478b-84c4-67c72a400e8f'	System	14 Dec 2020 04:33:38
User entered 'No (N)'	System	14 Dec 2020 04:33:38

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-12-13T21:33:33', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '559ac925-ebac-478b-84c4-67c72a400e8f' User entered '13 Dec 2020 21:33:33'	System	14 Dec 2020 04:33:38
	System	14 Dec 2020 04:33:38

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-12-21T18:53:32', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '34d8e943-2d09-4829-81a1-d8b65ffb1ca7'	System	22 Dec 2020 01:53:44
User entered 'No (N)'	System	22 Dec 2020 01:53:44



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Have you been exposed to someone with 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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-12-21T18:53:37', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '34d8e943-2d09-4829-81a1-d8b65ffb1ca7'	System	22 Dec 2020 01:53:44
User entered 'No (N)'	System	22 Dec 2020 01:53:44

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2020-12-21T18:53:41', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '34d8e943-2d09-4829-81a1-d8b65ffb1ca7' User entered '21 Dec 2020 18:53:41'	System	22 Dec 2020 01:53:44
	System	22 Dec 2020 01:53:44

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 19:38:32



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-01-03T16:20:21', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '26541bc9-6d29-4892-99f2-c57ea1dab6b4' User entered 'No (N)'	System	03 Jan 2021 23:20:33
	System	03 Jan 2021 23:20:33

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Have you been exposed to someone with 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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-01-03T16:20:25', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '26541bc9-6d29-4892-99f2-c57ea1dab6b4' User entered 'No (N)'	System	03 Jan 2021 23:20:33
	System	03 Jan 2021 23:20:33

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-01-03T16:20:30', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '26541bc9-6d29-4892-99f2-c57ea1dab6b4' User entered '03 Jan 2021 16:20:30'	System	03 Jan 2021 23:20:33
	System	03 Jan 2021 23:20:33

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-01-11T21:34:35', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '88a6760f-8e7f-4e72-91ab-97ecf3da44a8'	System	18 Jan 2021 14:45:25
User entered 'No (N)'	System	18 Jan 2021 14:45:25

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Have you been exposed to someone with 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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-01-11T21:34:39', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '88a6760f-8e7f-4e72-91ab-97ecf3da44a8'	System	18 Jan 2021 14:45:25
User entered 'No (N)'	System	18 Jan 2021 14:45:25



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-01-11T21:34:42', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '88a6760f-8e7f-4e72-91ab-97ecf3da44a8' User entered '11 Jan 2021 21:34:42'	System	18 Jan 2021 14:45:25
	System	18 Jan 2021 14:45:25

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-01-18T07:45:24', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '7c9ecc45-0409-436b-9461-deb2d2cd9e48' User entered 'No (N)'	System	18 Jan 2021 14:45:36
	System	18 Jan 2021 14:45:36

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Have you been exposed to someone with 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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-01-18T07:45:27', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '7c9ecc45-0409-436b-9461-deb2d2cd9e48'	System	18 Jan 2021 14:45:36
User entered 'No (N)'	System	18 Jan 2021 14:45:36

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-01-18T07:45:32', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '7c9ecc45-0409-436b-9461-deb2d2cd9e48' User entered '18 Jan 2021 07:45:32'	System	18 Jan 2021 14:45:36
	System	18 Jan 2021 14:45:36

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 19:38:32



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-01-24T07:35:25', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '7382372e-b230-45df-be88-f1470d50028e' User entered 'No (N)'	System	24 Jan 2021 14:35:35
	System	24 Jan 2021 14:35:35

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Have you been exposed to someone with 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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-01-24T07:35:28', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '7382372e-b230-45df-be88-f1470d50028e' User entered 'No (N)'	System	24 Jan 2021 14:35:35
	System	24 Jan 2021 14:35:35

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-01-24T07:35:31', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '7382372e-b230-45df-be88-f1470d50028e' User entered '24 Jan 2021 07:35:31'	System	24 Jan 2021 14:35:35
	System	24 Jan 2021 14:35:35

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 19:38:32



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-01-31T21:17:22', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'c20ec416-2183-4a3f-8720-323d48ba1559' User entered 'No (N)'	System	01 Feb 2021 04:17:33
	System	01 Feb 2021 04:17:33

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Have you been exposed to someone with 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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-01-31T21:17:25', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'c20ec416-2183-4a3f-8720-323d48ba1559' User entered 'No (N)'	System	01 Feb 2021 04:17:33
	System	01 Feb 2021 04:17:33

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-01-31T21:17:30', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'c20ec416-2183-4a3f-8720-323d48ba1559' User entered '31 Jan 2021 21:17:30'	System	01 Feb 2021 04:17:33
	System	01 Feb 2021 04:17:33

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-02-08T20:47:24', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'ff63968c-c984-439c-86a1-dd9064cc660f' User entered 'Yes (Y)'	System	09 Feb 2021 03:47:56
	System	09 Feb 2021 03:47:56

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Have you been exposed to someone with 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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-02-08T20:47:31', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'ff63968c-c984-439c-86a1-dd9064cc660f' User entered 'No (N)'	System	09 Feb 2021 03:47:56



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-02-08T20:47:34', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'ff63968c-c984-439c-86a1-dd9064cc660f' User entered 'No (N)'	System	09 Feb 2021 03:47:56

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-02-08T20:47:40', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'ff63968c-c984-439c-86a1-dd9064cc660f' User entered 'No (N)'	System	09 Feb 2021 03:47:56

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-02-08T20:47:52', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'ff63968c-c984-439c-86a1-dd9064cc660f'	System	09 Feb 2021 03:47:56
User entered '08 Feb 2021 20:47:52'	System	09 Feb 2021 03:47:56

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-02-14T09:39:34', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '0160dddf-fcf9-448c-b9c0-cc2142b94507'	System	14 Feb 2021 16:41:13
User entered 'Yes (Y)'	System	14 Feb 2021 16:41:13

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Have you been exposed to someone with 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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-02-14T09:39:39', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '0160dddf-fcf9-448c-b9c0-cc2142b94507'	System	14 Feb 2021 16:41:13
User entered 'No (N)'	System	14 Feb 2021 16:41:13



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-02-14T09:39:42', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '0160dddf-fcf9-448c-b9c0-cc2142b94507'	System	14 Feb 2021 16:41:13
User entered 'No (N)'	System	14 Feb 2021 16:41:13

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-02-14T09:41:04', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '0160dddf-fcf9-448c-b9c0-cc2142b94507'	System	14 Feb 2021 16:41:13
User entered 'No (N)'	System	14 Feb 2021 16:41:13

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-02-14T09:41:10', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '0160dddf-fcf9-448c-b9c0-cc2142b94507'	System	14 Feb 2021 16:41:13
User entered '14 Feb 2021 09:41:10'	System	14 Feb 2021 16:41:13

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-02-22T21:11:58', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'b6e279a2-17ce-4f89-a318-70fa5d8796d7' User entered 'No (N)'	System	23 Feb 2021 04:12:10
	System	23 Feb 2021 04:12:10

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Have you been exposed to someone with 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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-02-22T21:12:02', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'b6e279a2-17ce-4f89-a318-70fa5d8796d7' User entered 'No (N)'	System	23 Feb 2021 04:12:10



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-02-22T21:12:06', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'b6e279a2-17ce-4f89-a318-70fa5d8796d7' User entered '22 Feb 2021 21:12:06'	System	23 Feb 2021 04:12:10
	System	23 Feb 2021 04:12:10

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-03-01T14:22:25-07:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '564611af-e2b8-4d19-b18f-813fb051ac30'	System	01 Mar 2021 21:22:42
User entered 'Yes (Y)'	System	01 Mar 2021 21:22:42

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Have you been exposed to someone with 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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-03-01T14:22:28-07:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '564611af-e2b8-4d19-b18f-813fb051ac30'	System	01 Mar 2021 21:22:42
User entered 'No (N)'	System	01 Mar 2021 21:22:42

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-03-01T14:22:32-07:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '564611af-e2b8-4d19-b18f-813fb051ac30'	System	01 Mar 2021 21:22:42
User entered 'No (N)'	System	01 Mar 2021 21:22:42

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-03-01T14:22:36-07:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '564611af-e2b8-4d19-b18f-813fb051ac30'	System	01 Mar 2021 21:22:42
User entered 'No (N)'	System	01 Mar 2021 21:22:42



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-03-01T14:22:39-07:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '564611af-e2b8-4d19-b18f-813fb051ac30'	System	01 Mar 2021 21:22:42
User entered '01 Mar 2021 21:22:39'	System	01 Mar 2021 21:22:42

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-03-10T13:51:46-07:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '5c8d2299-3938-4898-aab4-0cf934fb18e0'	System	10 Mar 2021 20:51:56
User entered 'No (N)'	System	10 Mar 2021 20:51:56

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Have you been exposed to someone with 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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-03-10T13:51:49-07:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '5c8d2299-3938-4898-aab4-0cf934fb18e0'	System	10 Mar 2021 20:51:56
User entered 'No (N)'	System	10 Mar 2021 20:51:56

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-03-10T13:51:53-07:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '5c8d2299-3938-4898-aab4-0cf934fb18e0' User entered '10 Mar 2021 13:51:53'	System	10 Mar 2021 20:51:56
	System	10 Mar 2021 20:51:56

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 19:38:32



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-03-15T15:54:22-06:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'd12c2f5e-7f49-4491-8c0a-0136fd4cf4fb'	System	15 Mar 2021 21:54:32
User entered 'No (N)'	System	15 Mar 2021 21:54:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Have you been exposed to someone with 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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-03-15T15:54:25-06:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'd12c2f5e-7f49-4491-8c0a-0136fd4cf4fb'	System	15 Mar 2021 21:54:32
User entered 'No (N)'	System	15 Mar 2021 21:54:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-03-15T15:54:29-06:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'd12c2f5e-7f49-4491-8c0a-0136fd4cf4fb'	System	15 Mar 2021 21:54:32
User entered '15 Mar 2021 15:54:29'	System	15 Mar 2021 21:54:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 19:38:32



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-03-21T14:45:32-06:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'bffd9844-4592-4327-b010-eb5634046880'	System	21 Mar 2021 20:45:40
User entered 'No (N)'	System	21 Mar 2021 20:45:40

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Have you been exposed to someone with 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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-03-21T14:45:34-06:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'bffd9844-4592-4327-b010-eb5634046880'	System	21 Mar 2021 20:45:40
User entered 'No (N)'	System	21 Mar 2021 20:45:40

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-03-21T14:45:37-06:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'bffd9844-4592-4327-b010-eb5634046880'	System	21 Mar 2021 20:45:40
User entered '21 Mar 2021 14:45:37'	System	21 Mar 2021 20:45:40

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-03-28T13:45:12-06:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '462c2415-48e6-4da5-bc7e-83d266c86395'	System	28 Mar 2021 19:45:23
User entered 'No (N)'	System	28 Mar 2021 19:45:23

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Have you been exposed to someone with 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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-03-28T13:45:16-06:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '462c2415-48e6-4da5-bc7e-83d266c86395'	System	28 Mar 2021 19:45:23
User entered 'No (N)'	System	28 Mar 2021 19:45:23



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-03-28T13:45:19-06:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '462c2415-48e6-4da5-bc7e-83d266c86395'	System	28 Mar 2021 19:45:23
User entered '28 Mar 2021 13:45:19'	System	28 Mar 2021 19:45:23

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-04-05T13:35:07-06:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '3bd2fca2-36ce-4a4c-841a-2f8ca0671f80'	System	05 Apr 2021 19:35:18
User entered 'No (N)'	System	05 Apr 2021 19:35:18

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Have you been exposed to someone with 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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-04-05T13:35:10-06:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '3bd2fca2-36ce-4a4c-841a-2f8ca0671f80'	System	05 Apr 2021 19:35:18
User entered 'No (N)'	System	05 Apr 2021 19:35:18

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-04-05T13:35:13-06:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '3bd2fca2-36ce-4a4c-841a-2f8ca0671f80'	System	05 Apr 2021 19:35:18
User entered '05 Apr 2021 13:35:13'	System	05 Apr 2021 19:35:18

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 19:38:32



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-04-11T17:47:49-06:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '427c3d88-50df-412a-ac28-64b488ebad3b' User entered 'No (N)'	System	15 Apr 2021 21:47:45
	System	15 Apr 2021 21:47:45

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Have you been exposed to someone with 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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-04-11T17:47:53-06:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '427c3d88-50df-412a-ac28-64b488ebad3b' User entered 'No (N)'	System	15 Apr 2021 21:47:45
	System	15 Apr 2021 21:47:45

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-04-11T17:47:56-06:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '427c3d88-50df-412a-ac28-64b488ebad3b'	System	15 Apr 2021 21:47:45
User entered '11 Apr 2021 17:47:56'	System	15 Apr 2021 21:47:45

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 19:38:32



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-04-20T12:44:27-06:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '51950985-6bce-4a3e-952c-bc40ef320028'	System	20 Apr 2021 18:44:38
User entered 'No (N)'	System	20 Apr 2021 18:44:38

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Have you been exposed to someone with 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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-04-20T12:44:30-06:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '51950985-6bce-4a3e-952c-bc40ef320028'	System	20 Apr 2021 18:44:38
User entered 'No (N)'	System	20 Apr 2021 18:44:38

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-04-20T12:44:33-06:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '51950985-6bce-4a3e-952c-bc40ef320028' User entered '20 Apr 2021 12:44:33'	System	20 Apr 2021 18:44:38
	System	20 Apr 2021 18:44:38

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-04-26T06:42:56-06:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '1cb97d12-c3f0-47fc-88d6-d670d7cada88'	System	26 Apr 2021 12:43:06
User entered 'No (N)'	System	26 Apr 2021 12:43:06

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Have you been exposed to someone with 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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-04-26T06:42:59-06:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '1cb97d12-c3f0-47fc-88d6-d670d7cada88'	System	26 Apr 2021 12:43:06
User entered 'No (N)'	System	26 Apr 2021 12:43:06



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-04-26T06:43:03-06:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: '1cb97d12-c3f0-47fc-88d6-d670d7cada88'	System	26 Apr 2021 12:43:06
User entered '26 Apr 2021 06:43:03'	System	26 Apr 2021 12:43:06

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-05-02T20:13:05-06:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'ae6c977c-9c5a-41aa-bf62-c8990641b132'	System	03 May 2021 02:13:18
User entered 'No (N)'	System	03 May 2021 02:13:18

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

Have you been exposed to someone with 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 (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-05-02T20:13:08-06:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'ae6c977c-9c5a-41aa-bf62-c8990641b132'	System	03 May 2021 02:13:18
User entered 'No (N)'	System	03 May 2021 02:13:18

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-05-02T20:13:11-06:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'ae6c977c-9c5a-41aa-bf62-c8990641b132'	System	03 May 2021 02:13:18
User entered '02 May 2021 20:13:11'	System	03 May 2021 02:13:18

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 19:38:32



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 19:38:32



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 19:38:32



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 19:38:32



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 19:38:32



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 19:38:32



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 19:38:32



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 19:38:32



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 19:38:32



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 19:38:32



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 19:38:32



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 19:38:32



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 19:38:32



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 19:38:32



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 19:38:32



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 19:38:32



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 19:38:32



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 19:38:32



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 19:38:32



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 19:38:32



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 19:38:32



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 19:38:32



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 19:38:32



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 19:38:32



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 19:38:32



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 19:38:32



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 19:38:32



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 19:38:32



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 19:38:32



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '23 Oct 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '27 Oct 2022 23:59'	System	19 Nov 2020 19:38:32



**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '30 Oct 2022 00:01'	System	19 Nov 2020 19:38:32

**US3502045**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:55:38**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:38:32
Amendment Manager: User entered '03 Nov 2022 23:59'	System	19 Nov 2020 19:38:32

US3502045

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 07:55:38

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 18:52:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-03-01T14:24:09-07:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'a0029266-d0ea-4956-9343-d1d2c17aafdf'	System	01 Mar 2021 21:24:32
User entered 'Yes (Y)'	System	01 Mar 2021 21:24:32

US3502045

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 07:55:38**

Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:52:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-03-01T14:24:13-07:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'a0029266-d0ea-4956-9343-d1d2c17aafdf'	System	01 Mar 2021 21:24:32
User entered 'Yes (Y)'	System	01 Mar 2021 21:24:32

**US3502045**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 18:52:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B7D9396E-4A78-4630-99C5-DDAEC83BFBE9)', Time: '2021-03-01T14:24:22-07:00', User OID: 'PatientReportedOutcome (US3502045)', ODM File OID: 'a0029266-d0ea-4956-9343-d1d2c17aafdf' User entered '01 Mar 2021 21:24:22'	System	01 Mar 2021 21:24:32
	System	01 Mar 2021 21:24:32

**US3502045**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	(b) (4) Patrisha Adkins (b) (4) (b) (4)	25 Nov 2020 17:27:53

**US3502045**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '20 Nov 2020'	(b) (4) Patrisha Adkins (b) (4) (b) (4)	25 Nov 2020 17:27:53



**US3502045**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Contact Made (CONTACT MADE)'	Patrishia Adkins (b) (4)	25 Nov 2020 17:27:53

**US3502045**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered empty.	(b) (4)	
	Patrishia Adkins (b) (4)	25 Nov 2020 17:27:53
	(b) (4)	

**US3502045**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:55:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	(b) (4) Patrisha Adkins (b) (4) (b) (4)	25 Nov 2020 17:27:57

**US3502045**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:55:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:30:51
User entered 'I'	System	25 Nov 2020 17:27:57

**US3502045**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:29:43
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Dec 2020 21:10:49

**US3502045**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:29:43
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '23 Dec 2020'	(b) (4), (b) (6)	23 Dec 2020 21:10:49

**US3502045**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:29:43
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Dec 2020 21:10:49

**US3502045**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:29:43
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered empty.	(b) (4), (b) (6)	23 Dec 2020 21:10:49



**US3502045**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:55:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:29:43
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Dec 2020 21:10:57

**US3502045**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:55:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:29:43
User entered 'I'	System	23 Dec 2020 21:10:57

US3502045

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:29:43
User signature succeeded.	Thomas Campbell (b) (4)	19 Feb 2021 21:45:26
Signature has been broken.	Laurel Ware (b) (4)	17 Feb 2021 20:07:43
User entered 'Yes (Y)' reason for change: Data Entry Error	Laurel Ware (b) (4)	17 Feb 2021 20:07:43
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'No (N)'	Laurel Ware (b) (4)	28 Jan 2021 20:50:53

**US3502045**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:29:43
User signature succeeded.	Thomas Campbell (b) (4)	19 Feb 2021 21:45:26
Signature has been broken.	Laurel Ware (b) (4)	17 Feb 2021 20:07:43
User entered '26 Jan 2021' reason for change: Data Entry Error	Laurel Ware (b) (4)	17 Feb 2021 20:07:43
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered empty.	Laurel Ware (b) (4)	28 Jan 2021 20:50:53

US3502045

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:55:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:29:43
User signature succeeded.	Thomas Campbell (b) (4)	19 Feb 2021 21:45:26
Signature has been broken.	Laurel Ware (b) (4)	17 Feb 2021 20:07:43
User entered 'Contact Made (CONTACT MADE)'	Laurel Ware (b) (4)	17 Feb 2021 20:07:43
reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered empty.	Laurel Ware (b) (4)	28 Jan 2021 20:50:53

**US3502045**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:29:43
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'pt in for decision visit 1/26/21'	Laurel Ware (b) (4)	28 Jan 2021 20:50:53

US3502045

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:29:43
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Laurel Ware (b) (4)	28 Jan 2021 20:50:05

**US3502045**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:55:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:29:43
User entered 'I'	System	28 Jan 2021 20:50:05



**US3502045**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:29:43
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered 'Yes (Y)'	Laurel Ware (b) (4)	22 Feb 2021 22:06:14

**US3502045**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:29:43
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered '22 Feb 2021'	Laurel Ware (b) (4)	22 Feb 2021 22:06:14

**US3502045**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:29:43
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered 'Contact Made (CONTACT MADE)'	Laurel Ware (b) (4)	22 Feb 2021 22:06:14

**US3502045**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:29:43
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered empty.	Laurel Ware (b) (4)	22 Feb 2021 22:06:14

**US3502045**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:55:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:29:43
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered 'Yes (Y)'	Laurel Ware (b) (4)	22 Feb 2021 22:06:19

**US3502045**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:55:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 14:29:43
User entered 'I'	System	22 Feb 2021 22:06:19

US3502045

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:55:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:35
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
	(b) (4)	
User closed query 'Per CDM: Please complete the vital signs assessment form.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 04:29:22
Query 'Per CDM: Please complete the vital signs assessment form.' answered with 'has already been done' (Site from DM).	Suzanne Fiorillo (b) (4)	30 Mar 2021 15:14:49
	(b) (4)	
User opened query 'Per CDM: Please complete the vital signs assessment form.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 08:33:22
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	22 Mar 2021 21:07:38
	(b) (4)	

**US3502045**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:55:38**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:35
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
	(b) (4)	
User entered '22 Mar 2021'	Suzanne Fiorillo (b) (4)	22 Mar 2021 21:07:38
	(b) (4)	



**US3502045**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:55:38**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:35
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
	(b) (4)	
User entered 'Clinic (Clinic)'	Suzanne Fiorillo (b) (4)	22 Mar 2021 21:07:38
	(b) (4)	

**US3502045**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:55:38**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:35
User entered 'VISIT4'	System	22 Mar 2021 21:07:38

US3502045

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:35
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
	(b) (4)	
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	29 Mar 2021 23:30:42
	(b) (4)	

US3502045

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:35
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
	(b) (4)	
User entered '22 Mar 2021'	Suzanne Fiorillo (b) (4)	29 Mar 2021 23:30:42
	(b) (4)	

**US3502045**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:35
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
	(b) (4)	
User entered '10:55'	Suzanne Fiorillo (b) (4)	29 Mar 2021 23:30:42
	(b) (4)	

**US3502045**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:35
User entered '22 Mar 2021 10:55'	System	29 Mar 2021 23:30:42

US3502045

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:35
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
	(b) (4)	
User entered '36.6' C	Suzanne Fiorillo (b) (4)	29 Mar 2021 23:30:42
	(b) (4)	

**US3502045**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:35
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
	(b) (4)	
User entered 'Other (Other)'	Suzanne Fiorillo (b) (4)	29 Mar 2021 23:30:42
	(b) (4)	



**US3502045**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:35
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
	(b) (4)	
User entered 'temporal'	Suzanne Fiorillo (b) (4)	29 Mar 2021 23:30:42
	(b) (4)	

**US3502045**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:35
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
	(b) (4)	
User entered '61'	Suzanne Fiorillo (b) (4)	29 Mar 2021 23:30:42
	(b) (4)	

**US3502045**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:35
User entered 'bpm'	System	29 Mar 2021 23:30:42

US3502045

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:35
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
	(b) (4)	
User entered '14'	Suzanne Fiorillo (b) (4)	29 Mar 2021 23:30:42
	(b) (4)	

US3502045

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:35
User entered 'breaths/min'	System	29 Mar 2021 23:30:42

US3502045

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:35
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
	(b) (4)	
User entered '118'	Suzanne Fiorillo (b) (4)	29 Mar 2021 23:30:42
	(b) (4)	

**US3502045**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:35
User entered 'mmHg'	System	29 Mar 2021 23:30:42

US3502045

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:55:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:35
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
	(b) (4)	
User entered '60'	Suzanne Fiorillo (b) (4)	29 Mar 2021 23:30:42
	(b) (4)	



**US3502045**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:35
User entered 'mmHg'	System	29 Mar 2021 23:30:42

**US3502045**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:35

**US3502045**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:35

US3502045

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:55:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:35
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
	(b) (4)	
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	22 Mar 2021 21:07:48
	(b) (4)	

US3502045

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:55:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:35
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
	(b) (4)	
User entered '22 Mar 2021'	Suzanne Fiorillo (b) (4)	22 Mar 2021 21:07:48
	(b) (4)	

US3502045

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:35
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
	(b) (4)	
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	22 Mar 2021 21:08:00
	(b) (4)	

US3502045

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:35
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
	(b) (4)	
User entered '22 Mar 2021'	Suzanne Fiorillo (b) (4)	22 Mar 2021 21:08:00
	(b) (4)	

US3502045

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:35
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Mar 2021 15:50:22
User entered '11:10' reason for change: Data Entry Error	Suzanne Fiorillo (b) (4)	24 Mar 2021 15:50:22
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Mar 2021 21:08:00
User entered empty.	Suzanne Fiorillo (b) (4)	22 Mar 2021 21:08:00
	(b) (4)	



**US3502045**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:55:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:35
User entered '22 Mar 2021 11:10'	System	24 Mar 2021 15:50:22
User entered empty.	System	22 Mar 2021 21:08:00

US3502045

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:35
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
	(b) (4)	
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	22 Mar 2021 21:08:05
	(b) (4)	

**US3502045**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:55:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:56:35
User entered 'I'	System	22 Mar 2021 21:08:05

**US3502045**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 22:39:55
User entered 'Yes (Y)'	(b) (4) Laurel Ware (b) (4) (b) (4)	28 Apr 2021 21:04:08

**US3502045**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 22:39:55
	(b) (4)	
User entered '23 Apr 2021'	Laurel Ware (b) (4)	28 Apr 2021 21:04:08
	(b) (4)	

**US3502045**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 22:39:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Laurel Ware (b) (4) (b) (4)	28 Apr 2021 21:04:08

**US3502045**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 22:39:55
User entered empty.	(b) (4) Laurel Ware (b) (4)	28 Apr 2021 21:04:08
	(b) (4)	

**US3502045**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:55:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 22:39:55
	(b) (4)	
User entered 'Yes (Y)'	Laurel Ware (b) (4)	28 Apr 2021 21:04:16
	(b) (4)	



**US3502045**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:55:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	28 Apr 2021 21:04:16

**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:55:38**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:28:27

**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:55:38**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '26 Jan 2021'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:28:27

**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:55:38**

[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 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Clinic (Clinic)'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:28:27

**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:55:38**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User entered 'UNBLND_DECIDE'	System	26 Jan 2021 23:28:27

US3502045

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 07:55:38

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '26 Jan 2021'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:28:13

**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:55:38**

[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 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:50:36

**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:55:38**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:28:13



**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:55:38**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
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 17:50:36

US3502045

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 07:55:38

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '26 Jan 2021'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:28:13

**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:55:38**

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Placebo (Placebo)'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:28:13

US3502045

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 07:55:38

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Placebo (Placebo)'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:28:13

**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:55:38**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Placebo (Placebo)'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:28:13

**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:55:38**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:28:13

**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:55:38**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User entered '1'	System	26 Jan 2021 23:28:13

**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:55:38**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User entered 'I'	System	26 Jan 2021 23:28:13



US3502045

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:55:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered missing code ND - Not Done.	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:50:19

US3502045

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:55:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered missing code ND - Not Done.	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:50:19

**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 07:55:38**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User entered empty.	System	26 Jan 2021 23:50:19
DataPoint set to visible.	System	26 Jan 2021 23:28:13

US3502045

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:55:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered missing code ND - Not Done.	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:50:19

US3502045

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:55:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered missing code ND - Not Done.	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:50:19

**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 07:55:38**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User entered empty.	System	26 Jan 2021 23:50:19
DataPoint set to visible.	System	26 Jan 2021 23:28:13

**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User accepted default value 'Pre-Dose (PREDOSE)'	Suzanne Fiorillo (b) (4) (b) (4)	26 Jan 2021 23:50:19

US3502045

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:50:19



US3502045

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '26 Jan 2021'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:50:19

**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:55:38**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '15:46'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:50:19

**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User entered '26 Jan 2021 15:46'	System	26 Jan 2021 23:50:19

US3502045

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
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)	28 Jan 2021 07:06:01
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)	26 Jan 2021 23:50:33
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	26 Jan 2021 23:50:19
User entered '35.5' C	Suzanne Fiorillo (b) (4) (b) (4)	26 Jan 2021 23:50:19

US3502045

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Other (Other)'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:50:19

**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:55:38**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'temporal'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:50:19

US3502045

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '66'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:50:19

**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User entered 'bpm'	System	26 Jan 2021 23:50:19



US3502045

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '20'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:50:19

**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User entered 'breaths/min'	System	26 Jan 2021 23:50:19

US3502045

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '139'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:50:19

**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User entered 'mmHg'	System	26 Jan 2021 23:50:19

US3502045

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '63'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:50:19

**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User entered 'mmHg'	System	26 Jan 2021 23:50:19

US3502045

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:55:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered missing code ND - Not Done.	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:50:19

US3502045

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:55:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered missing code ND - Not Done.	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:50:19



**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 07:55:38**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User entered empty.	System	26 Jan 2021 23:50:19
DataPoint set to visible.	System	26 Jan 2021 23:28:13

**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User accepted default value 'Post-Dose (POSTDOSE)'	Suzanne Fiorillo (b) (4) (b) (4)	26 Jan 2021 23:50:19

US3502045

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:50:19

**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:55:38**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '26 Jan 2021'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:50:19

**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:55:38**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '16:44'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:50:19

**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User entered '26 Jan 2021 16:44'	System	26 Jan 2021 23:50:19

US3502045

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User closed query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	26 Jan 2021 23:51:01
Query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	26 Jan 2021 23:51:01
User entered '98' F reason for change: Data Entry Error	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:51:01
User opened query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	26 Jan 2021 23:50:19
User entered '98' C	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:50:19

US3502045

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Other (Other)'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:50:19



**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:55:38**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'temporal'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:50:19

US3502045

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '64'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:50:19

**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User entered 'bpm'	System	26 Jan 2021 23:50:19

US3502045

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '17'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:50:19

**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User entered 'breaths/min'	System	26 Jan 2021 23:50:19

US3502045

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '124'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:50:19

**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User entered 'mmHg'	System	26 Jan 2021 23:50:19

US3502045

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '74'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:50:19



**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User entered 'mmHg'	System	26 Jan 2021 23:50:19

US3502045

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:55:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:28:39

US3502045

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:55:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '26 Jan 2021'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:28:39

US3502045

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:28:55

US3502045

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered empty.	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:28:55

US3502045

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

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 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered empty.	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:28:55

**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:55:38**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User entered 'mRNA-1273'	System	26 Jan 2021 23:28:55
DataPoint set to visible.	System	26 Jan 2021 23:28:13

US3502045

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '26 Jan 2021'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:28:55



US3502045

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '16:14'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:28:55

**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:55:38**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User entered '26 Jan 2021 16:14'	System	26 Jan 2021 23:28:55

US3502045

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Left Arm (LEFT ARM)'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:28:55

**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:55:38**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User entered 'ONCE'	System	26 Jan 2021 23:28:55

**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:55:38**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User entered 'INTRAMUSCULAR'	System	26 Jan 2021 23:28:55

US3502045

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:51:22

US3502045

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:55:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '26 Jan 2021'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:51:22

**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:55:38**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '16:00'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:51:22



**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:55:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User entered '26 Jan 2021 16:00'	System	26 Jan 2021 23:51:22

**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 07:55:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:51:39

**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 07:55:38**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '26 Jan 2021'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:51:39

**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 07:55:38**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '16:01'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:51:39

**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 07:55:38**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User entered '26 Jan 2021 16:01'	System	26 Jan 2021 23:51:39

US3502045

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:55:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	26 Jan 2021 23:29:02

**US3502045**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:55:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User entered 'I'	System	26 Jan 2021 23:29:02

**US3502045**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered 'Yes (Y)'	Laurel Ware (b) (4)	22 Feb 2021 21:59:33



**US3502045**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered '02 Feb 2021'	Laurel Ware (b) (4)	22 Feb 2021 21:59:33

**US3502045**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered 'Contact Made (CONTACT MADE)'	Laurel Ware (b) (4)	22 Feb 2021 21:59:33

**US3502045**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered empty.	Laurel Ware (b) (4)	22 Feb 2021 21:59:33

**US3502045**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:55:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered 'Yes (Y)'	Laurel Ware (b) (4)	22 Feb 2021 21:59:39

**US3502045**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:55:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User entered 'I'	System	22 Feb 2021 21:59:39

**US3502045**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:55:38**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User entered 'I'	System	22 Feb 2021 21:59:39
DataPoint set to visible.	System	22 Feb 2021 21:59:39

**US3502045**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:55:38**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	25 Feb 2021 00:58:11

**US3502045**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:55:38**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered '24 Feb 2021'	Suzanne Fiorillo (b) (4)	25 Feb 2021 00:58:11



**US3502045**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:55:38**

[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 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered 'Clinic (Clinic)'	Suzanne Fiorillo (b) (4)	25 Feb 2021 00:58:11

**US3502045**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:55:38**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User entered 'OLD29'	System	25 Feb 2021 00:58:11

US3502045

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User accepted default value 'Pre-Dose (PREDOSE)'	Suzanne Fiorillo (b) (4) (b) (4)	25 Feb 2021 00:58:49

**US3502045**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	25 Feb 2021 00:58:49

**US3502045**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:55:38**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered '24 Feb 2021'	Suzanne Fiorillo (b) (4)	25 Feb 2021 00:58:49

**US3502045**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:55:38**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered '15:28'	Suzanne Fiorillo (b) (4)	25 Feb 2021 00:58:49

**US3502045**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User entered '24 Feb 2021 15:28'	System	25 Feb 2021 00:58:49

US3502045

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered '36.3' C	Suzanne Fiorillo (b) (4)	25 Feb 2021 00:58:49



**US3502045**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered 'Other (Other)'	Suzanne Fiorillo (b) (4)	25 Feb 2021 00:58:49

**US3502045**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:55:38**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered 'temporal'	Suzanne Fiorillo (b) (4)	25 Feb 2021 00:58:49

**US3502045**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered '63'	Suzanne Fiorillo (b) (4)	25 Feb 2021 00:58:49

**US3502045**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User entered 'bpm'	System	25 Feb 2021 00:58:49

US3502045

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered '14'	Suzanne Fiorillo (b) (4)	25 Feb 2021 00:58:49

**US3502045**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User entered 'breaths/min'	System	25 Feb 2021 00:58:49

US3502045

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered '112'	Suzanne Fiorillo (b) (4)	25 Feb 2021 00:58:49

**US3502045**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User entered 'mmHg'	System	25 Feb 2021 00:58:49



US3502045

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:55:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 05:04:24
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System).	Suzanne Fiorillo (b) (4) (b) (4)	25 Feb 2021 00:59:13
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		25 Feb 2021 00:58:49
User entered '59'	Suzanne Fiorillo (b) (4) (b) (4)	25 Feb 2021 00:58:49

**US3502045**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User entered 'mmHg'	System	25 Feb 2021 00:58:49

**US3502045**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User accepted default value 'Post-Dose (POSTDOSE)'	Suzanne Fiorillo (b) (4) (b) (4)	25 Feb 2021 00:58:49

**US3502045**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Suzanne Fiorillo (b) (4)	26 Feb 2021 00:07:08
User entered 'No (N)'	Suzanne Fiorillo (b) (4)	25 Feb 2021 00:58:49

US3502045

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered '24 Feb 2021' reason for change: Data Entry Error	(b) (4)	
	Suzanne Fiorillo (b) (4)	26 Feb 2021 00:07:08
User entered empty.	(b) (4)	
	Suzanne Fiorillo (b) (4)	25 Feb 2021 00:58:49
	(b) (4)	

**US3502045**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:55:38**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered '16:07' reason for change: Data Entry Error	Suzanne Fiorillo (b) (4)	26 Feb 2021 00:07:08
User entered empty.	Suzanne Fiorillo (b) (4)	25 Feb 2021 00:58:49

**US3502045**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User entered '24 Feb 2021 16:07'	System	26 Feb 2021 00:07:08
User entered empty.	System	25 Feb 2021 00:58:49

US3502045

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '36.9' C reason for change: Data Entry Error	System	26 Feb 2021 00:07:12
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Suzanne Fiorillo (b) (4)	26 Feb 2021 00:07:12
User entered '36.9' (non-conformant).	(b) (4)	
User entered empty.	System	26 Feb 2021 00:07:08
	Suzanne Fiorillo (b) (4)	26 Feb 2021 00:07:08
	(b) (4)	
	Suzanne Fiorillo (b) (4)	25 Feb 2021 00:58:49
	(b) (4)	



US3502045

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4)	26 Feb 2021 00:07:08
User entered empty.	Suzanne Fiorillo (b) (4)	25 Feb 2021 00:58:49
	(b) (4)	

**US3502045**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:55:38**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered 'temporal' reason for change: Data Entry Error	Suzanne Fiorillo (b) (4)	26 Feb 2021 00:07:08
User entered empty.	Suzanne Fiorillo (b) (4)	25 Feb 2021 00:58:49

**US3502045**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered '59' reason for change: Data Entry Error	Suzanne Fiorillo (b) (4)	26 Feb 2021 00:07:08
User entered empty.	Suzanne Fiorillo (b) (4)	25 Feb 2021 00:58:49

**US3502045**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User entered 'bpm'	System	26 Feb 2021 00:07:08
User entered empty.	System	25 Feb 2021 00:58:49

US3502045

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered '18' reason for change: Data Entry Error	(b) (4)	
	Suzanne Fiorillo (b) (4)	26 Feb 2021 00:07:08
User entered empty.	(b) (4)	
	Suzanne Fiorillo (b) (4)	25 Feb 2021 00:58:49
	(b) (4)	

**US3502045**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User entered 'breaths/min'	System	26 Feb 2021 00:07:08
User entered empty.	System	25 Feb 2021 00:58:49

US3502045

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:55:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered '100' reason for change: Data Entry Error	Suzanne Fiorillo (b) (4)	26 Feb 2021 00:07:08
User entered empty.	Suzanne Fiorillo (b) (4)	25 Feb 2021 00:58:49

**US3502045**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User entered 'mmHg'	System	26 Feb 2021 00:07:08
User entered empty.	System	25 Feb 2021 00:58:49



**US3502045**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered '62' reason for change: Data Entry Error	(b) (4)	
	Suzanne Fiorillo (b) (4)	26 Feb 2021 00:07:08
User entered empty.	(b) (4)	
	Suzanne Fiorillo (b) (4)	25 Feb 2021 00:58:49
	(b) (4)	

**US3502045**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User entered 'mmHg'	System	26 Feb 2021 00:07:08
User entered empty.	System	25 Feb 2021 00:58:49

**US3502045**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:55:38**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	25 Feb 2021 00:57:57

**US3502045**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:55:38**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered '24 Feb 2021'	Suzanne Fiorillo (b) (4)	25 Feb 2021 00:57:57

**US3502045**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:55:38**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	25 Feb 2021 00:57:41

**US3502045**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:55:38**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered empty.	Suzanne Fiorillo (b) (4)	25 Feb 2021 00:57:41

US3502045

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

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 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered empty.	Suzanne Fiorillo (b) (4)	25 Feb 2021 00:57:41

**US3502045**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:55:38**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User entered 'mRNA-1273'	System	25 Feb 2021 00:57:41
DataPoint set to visible.	System	22 Feb 2021 21:59:39



US3502045

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:55:38

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered '24 Feb 2021'	Suzanne Fiorillo (b) (4)	25 Feb 2021 00:57:41

**US3502045**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:55:38**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered '15:37'	Suzanne Fiorillo (b) (4)	25 Feb 2021 00:57:41

**US3502045**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:55:38**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User entered '24 Feb 2021 15:37'	System	25 Feb 2021 00:57:41

**US3502045**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:55:38**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered 'Left Arm (LEFT ARM)'	Suzanne Fiorillo (b) (4)	25 Feb 2021 00:57:41

**US3502045**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:55:38**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User entered 'ONCE'	System	25 Feb 2021 00:57:41

**US3502045**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:55:38**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User entered 'INTRAMUSCULAR'	System	25 Feb 2021 00:57:41

**US3502045**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:55:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	25 Feb 2021 00:57:47

**US3502045**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:55:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User entered 'I'	System	25 Feb 2021 00:57:47



**US3502045**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered 'Yes (Y)'	Laurel Ware (b) (4)	08 Mar 2021 04:04:56

**US3502045**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered '03 Mar 2021'	Laurel Ware (b) (4)	08 Mar 2021 04:04:56

**US3502045**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered 'Contact Made (CONTACT MADE)'	Laurel Ware (b) (4)	08 Mar 2021 04:04:56

**US3502045**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:55:38**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered empty.	Laurel Ware (b) (4)	08 Mar 2021 04:04:56

**US3502045**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:55:38**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered 'Yes (Y)'	Laurel Ware (b) (4)	08 Mar 2021 04:05:03

**US3502045**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:55:38**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:34
User entered 'I'	System	08 Mar 2021 04:05:03

**US3502045**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:55:38**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	22 Mar 2021 19:52:33

**US3502045**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:55:38**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
User entered '22 Mar 2021'	Suzanne Fiorillo (b) (4)	22 Mar 2021 19:52:33



**US3502045**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:55:38**

[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 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
User entered 'Clinic (Clinic)'	Suzanne Fiorillo (b) (4)	22 Mar 2021 19:52:33

**US3502045**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:55:38**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User entered 'OLD57'	System	22 Mar 2021 19:52:33

**US3502045**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	22 Mar 2021 19:53:08

**US3502045**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
User entered '22 Mar 2021'	Suzanne Fiorillo (b) (4)	22 Mar 2021 19:53:08

**US3502045**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
User entered '10:55'	Suzanne Fiorillo (b) (4)	22 Mar 2021 19:53:08

**US3502045**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User entered '22 Mar 2021 10:55'	System	22 Mar 2021 19:53:08

**US3502045**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
User entered '36.6' C	Suzanne Fiorillo (b) (4)	22 Mar 2021 19:53:08

**US3502045**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
User entered 'Other (Other)'	Suzanne Fiorillo (b) (4)	22 Mar 2021 19:53:08



**US3502045**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
User entered 'temporal'	Suzanne Fiorillo (b) (4)	22 Mar 2021 19:53:08

**US3502045**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
User entered '61'	Suzanne Fiorillo (b) (4)	22 Mar 2021 19:53:08

**US3502045**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User entered 'bpm'	System	22 Mar 2021 19:53:08

**US3502045**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
User entered '14'	Suzanne Fiorillo (b) (4)	22 Mar 2021 19:53:08

**US3502045**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User entered 'breaths/min'	System	22 Mar 2021 19:53:08

**US3502045**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
User entered '118'	Suzanne Fiorillo (b) (4)	22 Mar 2021 19:53:08

**US3502045**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User entered 'mmHg'	System	22 Mar 2021 19:53:08

**US3502045**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
User entered '60'	Suzanne Fiorillo (b) (4)	22 Mar 2021 19:53:08



**US3502045**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User entered 'mmHg'	System	22 Mar 2021 19:53:08

**US3502045**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	24 Apr 2021 14:52:32

**US3502045**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:55:38**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	24 Apr 2021 14:52:32

**US3502045**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:55:38**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	22 Mar 2021 19:53:18

**US3502045**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:55:38**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
User entered '22 Mar 2021'	Suzanne Fiorillo (b) (4)	22 Mar 2021 19:53:18

**US3502045**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:55:38**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
User entered 'Yes (Y)'	Suzanne Fiorillo (b) (4)	24 Mar 2021 15:49:59

**US3502045**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:55:38**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
User entered '22 Mar 2021'	Suzanne Fiorillo (b) (4)	24 Mar 2021 15:49:59

**US3502045**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:55:38**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User signature succeeded.	Thomas Campbell (b) (4)	08 Apr 2021 21:01:44
User entered '11:10'	Suzanne Fiorillo (b) (4)	24 Mar 2021 15:49:59



**US3502045**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:55:38**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:52:32
User entered '22 Mar 2021 11:10'	System	24 Mar 2021 15:49:59

US3502045

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 07:55:38

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:32
User closed query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary DOSE 1, NAUSEA lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 12:37:41
User closed query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary DOSE 1, FATIGUE lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 12:37:39
Query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary DOSE 1, NAUSEA lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked' answered with 'added to AE log' (Site from DM).	Laurel Ware (b) (4) (b) (4)	20 Apr 2021 19:58:19
Query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary DOSE 1, FATIGUE lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked' answered with 'added to AE log' (Site from DM).	Laurel Ware (b) (4) (b) (4)	20 Apr 2021 19:58:12

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 07:55:38

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary DOSE 1, NAUSEA lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 09:07:20
User opened query 'Per protocol any Solicited local or systemic AR lasting beyond 7 days post-injection must be entered into the participant's source document and must also be recorded as an AE in the participant's Adverse Event eCRF. Per subject's diary DOSE 1, FATIGUE lasted beyond day 7 post injection. Please reconcile and enter event as needed per Completion Guidelines (page 47/48) and ensure SAR box is checked' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 09:07:02
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:07:59
User entered 'Yes (Y)'	Josie Marshall (b) (4) (b) (4)	21 Sep 2020 20:42:31

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:55:38**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4)	03 Nov 2020 17:12:01
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 14:54:39
User entered		25 Sep 2020 14:54:33
'USA-US080-2020-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	25 Sep 2020 14:54:33

US3502045

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 17:12:01
User closed query 'Per DM CLR: Please note this AE overlaps with AE #1. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification.' (Site from DM).		28 Oct 2020 17:19:26
User closed query 'Per DM CLR: Please confirm if this AE is a worsening of the same condition noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 17:19:16
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine aggravated - version MedDRA\23.0.	Coder Import (b) (4)	23 Oct 2020 20:20:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	
Query 'Per DM CLR: Please confirm if this AE is a worsening of the same condition noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' answered with 'done' (Site from DM).	Coder Import (b) (4)	23 Oct 2020 20:20:39
	(b) (4)	
Query 'Per DM CLR: Please confirm if this AE is a worsening of the same condition noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' answered with 'done' (Site from DM).	Josie Marshall (b) (4)	23 Oct 2020 20:19:48
	(b) (4)	
Data point term sent to Coder	System	23 Oct 2020 20:19:42
Coding entries removed.	Josie Marshall (b) (4)	23 Oct 2020 20:19:41
	(b) (4)	
User entered 'MIGRAINE exacerbation' reason for change: Data Entry Error	Josie Marshall (b) (4)	23 Oct 2020 20:19:41
	(b) (4)	
Query 'Per DM CLR: Please note this AE overlaps with AE #1. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification.' answered with 'done' (Site from DM).	Josie Marshall (b) (4)	23 Oct 2020 19:17:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note this AE overlaps with AE #1. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 05:12:14
User opened query 'Per DM CLR: Please confirm if this AE is a worsening of the same condition noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 05:12:06
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 16:12:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Sep 2020 16:12:24
Data point term sent to Coder	System	24 Sep 2020 16:10:32
User entered 'Migraine'	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:09:40

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:12:01
User entered 'Yes (Y)'	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:09:40

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:12:01
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:09:40



**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:12:01
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:09:40

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:12:01
User entered '16 Sep 2020' reason for change: Data Entry Error	Josie Marshall (b) (4)	23 Oct 2020 19:15:25
User entered '22 Sep 2020'	Josie Marshall (b) (4)	24 Sep 2020 16:09:40

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:12:01
User entered empty.	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:09:40

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:55:38**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 16:09:40

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:12:01
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:09:40

US3502045

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:12:01
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	24 Sep 2020 16:22:31
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	24 Sep 2020 16:22:31
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	24 Sep 2020 16:09:40
User entered '23 Sep 2020'	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:09:40

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:55:38**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:12:01
User entered empty.	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:09:40

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:55:38**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Sep 2020 16:09:40



**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:12:01
User entered 'Grade 3/Severe (Grade 3/Severe)'	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:09:40

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:12:01
User entered 'Yes (Y)'	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:09:40

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:12:01
User entered '0'	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:09:40

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 17:12:01
User entered '0'	Josie Marshall (b) (4)	24 Sep 2020 16:09:40
	(b) (4)	

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:12:01
User entered 'I'	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:09:40

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:55:38**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:12:01
User entered '22 Sep 2020'	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:09:40

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:55:38**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:12:01
User entered '23 Sep 2020'	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:09:40

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:12:01
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:09:40



**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:12:01
User entered empty.	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:09:40

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:12:01
User entered '0'	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:09:40

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:12:01
User entered '0'	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:09:40

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:12:01
User entered '0'	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:09:40

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:12:01
User entered 'Not Related (NOT RELATED)'	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:09:40

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:12:01
User entered 'Not Related (NOT RELATED)'	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:09:40

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:12:01
User entered 'None (NONE)'	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:09:40

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:55:38**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:12:01
User entered '0'	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:09:40



**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:12:01
User entered 'I'	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:09:40

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 17:12:01
User entered '0'	Josie Marshall (b) (4)	24 Sep 2020 16:09:40
	(b) (4)	

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:12:01
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:22:31
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:09:40

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:55:38**

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 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:12:01
User entered empty.	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:09:40



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PT SUFFERS FROM MIGRAINES AND IS DOCUMENTED IN HISTORY PRIOR TO ENROLLING INTO TRIAL. SHE RECEIVED HER FIRST DOSE ON 04SEP2020. PT PRESENTED TO LOCAL ED ON 16SEP2020 FOR COMPLAINT OF ACUTE MIGRAINE. SHE WAS TREATED IN ED AND DISCHARGED HOME. PT RETURNED TO ED ON 22SEP2020 WITH COMPLAINT OF MIGRAINE PAIN THAT WARRANTED HIGHER LEVEL OF CARE. PT KEPT OVERNIGHT FOR OBSERVATION AND HAD MRI COMPLETED. MRI OF BRAIN WITH AND WITHOUT CONTRAST WAS UNREMARKABLE AND PT DISCHARGED ON 23SEP2020 AFTER NOTING IMPROVEMENT IN SYMPTOMS. SHE WAS DIRECTED TO FOLLOW-UP WITH HER NEUROLOGIST WHO HAD CONSULTED WITH ED STAFF AND FLOOR HOSPITALIST TO GUIDE TREATMENT PLAN. Pt reports that she does not have known triggers for exacerbation of migraine history. She reports that often times she can simply "wake-up" with a migraine or not have any warning whatsoever. she does not experience auras, and is unable to identify any known risk factors including diet, stress, changes in weather or fatigue.'	Josie Marshall (b) (4)	23 Oct 2020 20:24:54
reason for change: Data Entry Error Query 'PV Query: Please consider merging the two events of migraine (AE and SAE) into one SAE and add all details regarding both events in narrative section.' answered with 'done' (Site from Safety).	Josie Marshall (b) (4)	23 Oct 2020 19:17:16
User opened query 'PV Query: Please consider merging the two events of migraine (AE and SAE) into one SAE and add all details regarding both events in narrative section.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 17:49:19
User opened query 'PV Query: Was a trigger or underlying cause noted for the migraine.' (Site from Safety).	(b) (4), (b) (6)	02 Oct 2020 17:40:09
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	24 Sep 2020 16:28:40

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:55:38

[Narrative](#)

Audit	User	Time (GMT)
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	24 Sep 2020 16:28:40
User entered 'Pt suffers from migraines and is documented in history prior to enrolling into trial. she received her first dose on 04SEP2020. Pt presented to local ED on 16SEP2020 for complaint of acute migraine. She was treated in ED and discharged home. Pt returned to ED on 22SEP2020 with complaint of migraine pain that warranted higher level of care. Pt kept overnight for observation and had MRI completed. MRI of brain with and without contrast was unremarkable and pt discharged on 23SEP2020 after noting improvement in symptoms. She was directed to follow-up with her neurologist who had consulted with ED staff and floor hospitalist to guide treatment plan.' reason for change: Data Entry Error	Josie Marshall (b) (4)	24 Sep 2020 16:28:40
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	24 Sep 2020 16:09:40
User entered empty.	Josie Marshall (b) (4)	24 Sep 2020 16:09:40

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 16:09:40



**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Sep 2020 16:09:40

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Sep 2020 16:09:40

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:25

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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Milk allergy, LLT: Milk allergy - version MedDRA\\23.0.	Coder Import (b) (4)	26 Nov 2020 08:01:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	26 Nov 2020 08:01:40
Data point term sent to Coder	System	25 Nov 2020 17:31:06
User entered 'Milk Allergy Diagnosis'	Patrishia Adkins (b) (4)	25 Nov 2020 17:30:54

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:55:38**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered 'Yes (Y)'	Patrishia Adkins (b) (4)	25 Nov 2020 17:30:54

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:55:38**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered 'No (N)'	Patrishia Adkins (b) (4)	25 Nov 2020 17:30:54

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered 'No (N)'	Patrishia Adkins (b) (4)	25 Nov 2020 17:30:54

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered '12 Oct 2020'	Patrishia Adkins (b) (4)	25 Nov 2020 17:30:54



**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:55:38**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered empty.	Patrishia Adkins (b) (4)	25 Nov 2020 17:30:54

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:55:38**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:25
User entered empty.	System	25 Nov 2020 17:30:54

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Folder: Adverse Events

Form: Adverse Events (3)

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	25 Nov 2020 17:32:13
User entered 'No (N)' reason for change: Data Entry Error	Patrishia Adkins (b) (4)	25 Nov 2020 17:32:13
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	25 Nov 2020 17:31:56
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 17:31:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 17:31:35
User entered 'Yes (Y)' reason for change: Data Entry Error	Patrishia Adkins (b) (4)	25 Nov 2020 17:31:35
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 17:30:54
User entered empty.	Patrishia Adkins (b) (4)	25 Nov 2020 17:30:54

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	25 Nov 2020 17:31:56
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	25 Nov 2020 17:31:56
User entered '21 Nov 2020' reason for change: Data Entry Error	Patrishia Adkins (b) (4)	25 Nov 2020 17:31:56
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	25 Nov 2020 17:31:35
User entered empty; reason for change Data Entry Error	System	25 Nov 2020 17:31:35
User entered '20 Nov 2020'	Patrishia Adkins (b) (4)	25 Nov 2020 17:31:35
	(b) (4)	25 Nov 2020 17:30:54
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered empty.	Patrishia Adkins (b) (4)	25 Nov 2020 17:30:54

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:25
User entered empty.	System	25 Nov 2020 17:30:54

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Patrishia Adkins (b) (4)	25 Nov 2020 17:30:54

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered 'No (N)'	Patrishia Adkins (b) (4)	25 Nov 2020 17:30:54



**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered '0'	Patrishia Adkins (b) (4)	25 Nov 2020 17:30:54

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:55:38**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered '0'	Patrishia Adkins (b) (4)	25 Nov 2020 17:30:54

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:55:38**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered '0'	Patrishia Adkins (b) (4)	25 Nov 2020 17:30:54

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:55:38**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered empty.	Patrishia Adkins (b) (4)	25 Nov 2020 17:30:54

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

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**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered empty.	Patrishia Adkins (b) (4)	25 Nov 2020 17:30:54

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered empty.	Patrishia Adkins (b) (4)	25 Nov 2020 17:30:54

**US3502045**

**Folder: Adverse Events**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered empty.	Patrishia Adkins (b) (4)	25 Nov 2020 17:30:54

**US3502045**

**Folder: Adverse Events**

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered '0'	Patrishia Adkins (b) (4)	25 Nov 2020 17:30:54



**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered '0'	Patrishia Adkins (b) (4)	25 Nov 2020 17:30:54

**US3502045**

**Folder: Adverse Events**

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered '0'	Patrishia Adkins (b) (4)	25 Nov 2020 17:30:54

**US3502045**

**Folder: Adverse Events**

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered 'Not Related (NOT RELATED)'	Patrishia Adkins (b) (4)	25 Nov 2020 17:30:54

**US3502045**

**Folder: Adverse Events**

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered 'Not Related (NOT RELATED)'	Patrishia Adkins (b) (4)	25 Nov 2020 17:30:54

**US3502045**

**Folder: Adverse Events**

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered 'None (NONE)'	Patrishia Adkins (b) (4)	25 Nov 2020 17:30:54

**US3502045**

**Folder: Adverse Events**

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered 'I'	Patrishia Adkins (b) (4)	25 Nov 2020 17:30:54

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**Folder: Adverse Events**

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered '0'	Patrishia Adkins (b) (4)	25 Nov 2020 17:30:54

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**Folder: Adverse Events**

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered '0'	Patrishia Adkins (b) (4)	25 Nov 2020 17:30:54



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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)'	Patrishia Adkins (b) (4)	25 Nov 2020 17:30:54

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**Folder: Adverse Events**

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered 'Continued diet modification'	Patrishia Adkins (b) (4)	25 Nov 2020 17:30:54

**US3502045**

**Folder: Adverse Events**

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered empty.	Patrishia Adkins (b) (4)	25 Nov 2020 17:30:54

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:25
User entered '0'	System	25 Nov 2020 17:30:54

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:55:38**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:25
User entered 'I'	System	25 Nov 2020 17:30:54

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 07:55:38**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:25

US3502045

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User closed query 'Per MM: please confirm if the subject experienced symptoms of COVID-19. If yes, please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 03:25:19
Query 'Per MM: please confirm if the subject experienced symptoms of COVID-19. If yes, please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'PD captured' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 22:42:55
User opened query 'Per MM: please confirm if the subject experienced symptoms of COVID-19. If yes, please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 09:05:06
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 17:35:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 17:35:22
Data point term sent to Coder	System	25 Nov 2020 17:34:12
User entered 'Seasonal Allergy Exacerbation'	Patrishia Adkins (b) (4) (b) (4)	25 Nov 2020 17:33:53

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:55:38**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered 'Yes (Y)'	Patrishia Adkins (b) (4)	25 Nov 2020 17:33:53
	(b) (4)	



**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:55:38**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered 'No (N)'	Patrishia Adkins (b) (4)	25 Nov 2020 17:33:53
	(b) (4)	

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:55:38**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered 'No (N)'	Patrishia Adkins (b) (4)	25 Nov 2020 17:33:53
	(b) (4)	

US3502045

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered '15 Oct 2020'	Patrishia Adkins (b) (4)	25 Nov 2020 17:33:53
	(b) (4)	

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:55:38**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered empty.	Patrishia Adkins (b) (4)	25 Nov 2020 17:33:53
	(b) (4)	

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:55:38**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Nov 2020 17:33:53

US3502045

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 12:28:41
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' answered with 'still ongoing' (Site from DM).	Suzanne Fiorillo (b) (4) (b) (4)	22 Feb 2021 23:00:06
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 23:14:32
User entered 'Yes (Y)'	Patrishia Adkins (b) (4) (b) (4)	25 Nov 2020 17:33:53

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:55:38**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered empty.	Patrishia Adkins (b) (4)	25 Nov 2020 17:33:53
	(b) (4)	

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:55:38**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered empty.	Patrishia Adkins (b) (4)	25 Nov 2020 17:33:53
	(b) (4)	



**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:55:38**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Nov 2020 17:33:53

US3502045

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

Severity

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User closed query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Feb 2021 12:28:32
Query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification.' answered with 'still considered grade 1' (Site from DM).	Suzanne Fiorillo (b) (4) (b) (4)	22 Feb 2021 23:01:09
User opened query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 23:14:38
User entered 'Grade 1/Mild (Grade 1/Mild)'	Patrishia Adkins (b) (4) (b) (4)	25 Nov 2020 17:33:53

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:55:38**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered 'No (N)'	Patrishia Adkins (b) (4)	25 Nov 2020 17:33:53
	(b) (4)	

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:55:38**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered '0'	Patrishia Adkins (b) (4)	25 Nov 2020 17:33:53
	(b) (4)	

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:55:38**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered '0'	Patrishia Adkins (b) (4)	25 Nov 2020 17:33:53
	(b) (4)	

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:55:38**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered '0'	Patrishia Adkins (b) (4)	25 Nov 2020 17:33:53
	(b) (4)	

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:55:38**

**Hospital Admission Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered empty.	Patrishia Adkins (b) (4)	25 Nov 2020 17:33:53
	(b) (4)	

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:55:38**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered empty.	Patrishia Adkins (b) (4)	25 Nov 2020 17:33:53
	(b) (4)	



**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:55:38**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered empty.	Patrishia Adkins (b) (4)	25 Nov 2020 17:33:53
	(b) (4)	

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:55:38**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered empty.	Patrishia Adkins (b) (4)	25 Nov 2020 17:33:53
	(b) (4)	

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:55:38**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered '0'	Patrishia Adkins (b) (4)	25 Nov 2020 17:33:53
	(b) (4)	

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:55:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered '0'	Patrishia Adkins (b) (4)	25 Nov 2020 17:33:53
	(b) (4)	

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:55:38**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered '0'	Patrishia Adkins (b) (4)	25 Nov 2020 17:33:53
	(b) (4)	

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:55:38**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Patrishia Adkins (b) (4)	25 Nov 2020 17:33:53
	(b) (4)	

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:55:38**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Patrishia Adkins (b) (4)	25 Nov 2020 17:33:53
	(b) (4)	

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:55:38**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered 'None (NONE)'	Patrishia Adkins (b) (4)	25 Nov 2020 17:33:53
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:55:38**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered '0'	Patrishia Adkins (b) (4)	25 Nov 2020 17:33:53
	(b) (4)	

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:55:38**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered 'I'	Patrishia Adkins (b) (4)	25 Nov 2020 17:33:53
	(b) (4)	

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:55:38**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered '0'	Patrishia Adkins (b) (4)	25 Nov 2020 17:33:53
	(b) (4)	

US3502045

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:55:38

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
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	25 Nov 2020 17:34:09
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	System	25 Nov 2020 17:34:09
User opened query 'Data is required. Please complete.' (Site from System).	Patrishia Adkins (b) (4)	25 Nov 2020 17:34:09
User entered empty.	(b) (4)	
	System	25 Nov 2020 17:33:53
	Patrishia Adkins (b) (4)	25 Nov 2020 17:33:53
	(b) (4)	

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:55:38**

[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 19:39:04
	(b) (4)	
User entered empty.	Patrishia Adkins (b) (4)	25 Nov 2020 17:33:53
	(b) (4)	

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:55:38**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered empty.	Patrishia Adkins (b) (4)	25 Nov 2020 17:33:53
	(b) (4)	

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:55:38**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Nov 2020 17:33:53

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 07:55:38**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Nov 2020 17:33:53



**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:55:38**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27

US3502045

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 07:55:38

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 19:57:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 19:57:44
Data point term sent to Coder	System	20 Apr 2021 19:56:50
User entered 'fatigue'	Laurel Ware (b) (4)	20 Apr 2021 19:56:12

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered 'No (N)'	Laurel Ware (b) (4)	20 Apr 2021 19:56:12

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered 'Yes (Y)'	Laurel Ware (b) (4)	20 Apr 2021 19:56:12

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered 'No (N)'	Laurel Ware (b) (4)	20 Apr 2021 19:56:12

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered '02 Sep 2020'	Laurel Ware (b) (4)	20 Apr 2021 19:56:12

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered empty.	Laurel Ware (b) (4)	20 Apr 2021 19:56:12

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:55:38**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User entered empty.	System	20 Apr 2021 19:56:12



**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered 'No (N)'	Laurel Ware (b) (4)	20 Apr 2021 19:56:12

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:55:38**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered '06 Sep 2020'	Laurel Ware (b) (4)	20 Apr 2021 19:56:12

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:55:38**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered empty.	Laurel Ware (b) (4)	20 Apr 2021 19:56:12

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:55:38**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User entered empty.	System	20 Apr 2021 19:56:12

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered 'Grade 1/Mild (Grade 1/Mild)'	Laurel Ware (b) (4)	20 Apr 2021 19:56:12

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered 'No (N)'	Laurel Ware (b) (4)	20 Apr 2021 19:56:12

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered '0'	Laurel Ware (b) (4)	20 Apr 2021 19:56:12

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered '0'	Laurel Ware (b) (4)	20 Apr 2021 19:56:12



**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered '0'	Laurel Ware (b) (4)	20 Apr 2021 19:56:12

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:55:38**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered empty.	Laurel Ware (b) (4)	20 Apr 2021 19:56:12

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered empty.	Laurel Ware (b) (4)	20 Apr 2021 19:56:12

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered empty.	Laurel Ware (b) (4)	20 Apr 2021 19:56:12

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered empty.	Laurel Ware (b) (4)	20 Apr 2021 19:56:12

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered '0'	Laurel Ware (b) (4)	20 Apr 2021 19:56:12

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered '0'	Laurel Ware (b) (4)	20 Apr 2021 19:56:12

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered '0'	Laurel Ware (b) (4)	20 Apr 2021 19:56:12



**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered 'Related (RELATED)'	Laurel Ware (b) (4)	20 Apr 2021 19:56:12

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered 'Not Related (NOT RELATED)'	Laurel Ware (b) (4)	20 Apr 2021 19:56:12

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered 'None (NONE)'	Laurel Ware (b) (4)	20 Apr 2021 19:56:12

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:55:38**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered 'I'	Laurel Ware (b) (4)	20 Apr 2021 19:56:12

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered '0'	Laurel Ware (b) (4)	20 Apr 2021 19:56:12

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered '0'	Laurel Ware (b) (4)	20 Apr 2021 19:56:12

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Laurel Ware (b) (4)	20 Apr 2021 19:56:12

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:55:38**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered empty.	Laurel Ware (b) (4)	20 Apr 2021 19:56:12



**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered empty.	Laurel Ware (b) (4)	20 Apr 2021 19:56:12

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User entered '0'	System	20 Apr 2021 19:56:12

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27
User entered '0'	System	20 Apr 2021 19:56:12

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:27

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 07:55:38**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:30

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Folder: Adverse Events

Form: Adverse Events (6)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:30
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 19:58:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 19:58:30
Data point term sent to Coder	System	20 Apr 2021 19:57:52
User entered 'nausea'	Laurel Ware (b) (4)	20 Apr 2021 19:57:52

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 07:55:38**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:30
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered 'No (N)'	Laurel Ware (b) (4)	20 Apr 2021 19:57:52

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 07:55:38**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:30
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered 'Yes (Y)'	Laurel Ware (b) (4)	20 Apr 2021 19:57:52



**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:30
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered 'No (N)'	Laurel Ware (b) (4)	20 Apr 2021 19:57:52

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:30
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered '01 Sep 2020'	Laurel Ware (b) (4)	20 Apr 2021 19:57:52

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 07:55:38**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:30
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered empty.	Laurel Ware (b) (4)	20 Apr 2021 19:57:52

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 07:55:38**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:30
User entered empty.	System	20 Apr 2021 19:57:52

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 07:55:38**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:30
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered 'No (N)'	Laurel Ware (b) (4)	20 Apr 2021 19:57:52

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

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*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:30
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered '05 Sep 2020'	Laurel Ware (b) (4)	20 Apr 2021 19:57:52

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 07:55:38**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:30
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered empty.	Laurel Ware (b) (4)	20 Apr 2021 19:57:52

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 07:55:38**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:30
User entered empty.	System	20 Apr 2021 19:57:52



**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 07:55:38**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:30
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered 'Grade 1/Mild (Grade 1/Mild)'	Laurel Ware (b) (4)	20 Apr 2021 19:57:52

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 07:55:38**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:30
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered 'No (N)'	Laurel Ware (b) (4)	20 Apr 2021 19:57:52

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 07:55:38**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:30
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered '0'	Laurel Ware (b) (4)	20 Apr 2021 19:57:52

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 07:55:38**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:30
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered '0'	Laurel Ware (b) (4)	20 Apr 2021 19:57:52

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 07:55:38**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:30
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered '0'	Laurel Ware (b) (4)	20 Apr 2021 19:57:52

US3502045

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 07:55:38

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:30
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered empty.	Laurel Ware (b) (4)	20 Apr 2021 19:57:52

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 07:55:38**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:30
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered empty.	Laurel Ware (b) (4)	20 Apr 2021 19:57:52

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 07:55:38**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:30
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered empty.	Laurel Ware (b) (4)	20 Apr 2021 19:57:52



**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 07:55:38**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:30
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered empty.	Laurel Ware (b) (4)	20 Apr 2021 19:57:52

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 07:55:38**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:30
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered '0'	Laurel Ware (b) (4)	20 Apr 2021 19:57:52

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 07:55:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:30
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered '0'	Laurel Ware (b) (4)	20 Apr 2021 19:57:52

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 07:55:38**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:30
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered '0'	Laurel Ware (b) (4)	20 Apr 2021 19:57:52

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 07:55:38**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:30
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered 'Related (RELATED)'	Laurel Ware (b) (4)	20 Apr 2021 19:57:52

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 07:55:38**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:30
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered 'Not Related (NOT RELATED)'	Laurel Ware (b) (4)	20 Apr 2021 19:57:52

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 07:55:38**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:30
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered 'None (NONE)'	Laurel Ware (b) (4)	20 Apr 2021 19:57:52

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 07:55:38**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:30
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered 'I'	Laurel Ware (b) (4)	20 Apr 2021 19:57:52



**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 07:55:38**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:30
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered '0'	Laurel Ware (b) (4)	20 Apr 2021 19:57:52

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 07:55:38**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:30
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered '0'	Laurel Ware (b) (4)	20 Apr 2021 19:57:52

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 07:55:38**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:30
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Laurel Ware (b) (4)	20 Apr 2021 19:57:52

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 07:55:38**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:30
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered empty.	Laurel Ware (b) (4)	20 Apr 2021 19:57:52

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 07:55:38**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:30
User signature succeeded.	Thomas Campbell (b) (4)	28 Apr 2021 10:46:51
User entered empty.	Laurel Ware (b) (4)	20 Apr 2021 19:57:52

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 07:55:38**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:30
User entered '0'	System	20 Apr 2021 19:57:52

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 07:55:38**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:30
User entered '0'	System	20 Apr 2021 19:57:52

**US3502045**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 07:55:38**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:17:30



US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 07:55:38

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:32
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).		08 Apr 2021 09:04:09
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' answered with 'this was marked yes in error, no cosmetic injections' (Site from DM).	Laurel Ware (b) (4) (b) (4)	06 Apr 2021 20:47:57
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 11:54:51
Query 'Per CDM: Dermal Filler is YES, but no corresponding Con Med or Procedure appears to indicate a dermal filler. Please reconcile or provide clarification.' canceled (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 11:54:41
User opened query 'Per CDM: Dermal Filler is YES, but no corresponding Con Med or Procedure appears to indicate a dermal filler. Please reconcile or provide clarification.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 17:53:45
Un-reviewed for Data Management.	(b) (4), (b) (6)	19 Mar 2021 17:53:11
Reviewed for Data Management.		19 Mar 2021 17:53:07

US3502045

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 10 Jun 2021 07:55:38**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:13:17
User entered 'Yes (Y)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:37:10

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:55:38

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: TOPIRAMATE, PRODUCTSYNONYM: TROKENDI - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Oct 2020 10:17:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Oct 2020 10:17:30
Data point term sent to Coder Coding entries removed.	System Josie Marshall (b) (4) (b) (4)	23 Oct 2020 19:03:19 23 Oct 2020 19:03:04
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: TOPIRAMATE, PRODUCTSYNONYM: TROKENDI - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 12:58:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 12:58:42
Data point term sent to Coder User entered 'trokendi'	System Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:38:51 31 Aug 2020 19:37:52

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User closed query 'Per DM CLR: Prophylaxis is YES. Please review this entry as there is an MH recorded that matches this medication and used within the same timeframe.Update entry on PROPHYLAXIS or provide explanation' (Site from DM).		27 Oct 2020 05:04:41
Query 'Per DM CLR: Prophylaxis is YES. Please review this entry as there is an MH recorded that matches this medication and used within the same timeframe.Update entry on PROPHYLAXIS or provide explanation' answered with 'Pt suffers from migraines, med is being used to prevent more. ' (Site from DM).	Josie Marshall (b) (4)	23 Oct 2020 19:02:56
	(b) (4)	
User opened query 'Per DM CLR: Prophylaxis is YES. Please review this entry as there is an MH recorded that matches this medication and used within the same timeframe.Update entry on PROPHYLAXIS or provide explanation' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 12:25:30
User entered 'Yes (Y)'	Josie Marshall (b) (4)	31 Aug 2020 19:37:52
	(b) (4)	

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'MIGRAINE prevention' reason for change: Data Entry Error	Josie Marshall (b) (4) (b) (4)	23 Oct 2020 19:03:04
User entered 'migraines'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:37:52

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:55:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '50' reason for change: Data Entry Error	Josie Marshall (b) (4)	31 Aug 2020 19:38:49
User entered '4.5'	Josie Marshall (b) (4)	31 Aug 2020 19:37:52

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'mg (mg)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:37:52

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:55:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:37:52



US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:55:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'three times daily (TID)' reason for change: Data Entry Error	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:38:49
User entered 'once daily (QD)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:37:52

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:55:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:37:52

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Oral (ORAL)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:37:52

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:55:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:37:52

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'un UNK 2007'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:37:52

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '0'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:37:52

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Yes (Y)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:37:52

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:55:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:37:52



US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:37:52

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	31 Aug 2020 19:38:49
User entered '1'	System	31 Aug 2020 19:37:52

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 19:37:52

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 19:37:52

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:55:38

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN OPIOID DEPENDENCE, PRODUCT: NALTREXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 06:19:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 06:19:46
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
Data point term sent to Coder	System	23 Oct 2020 19:03:19
Coding entries removed.	Josie Marshall (b) (4)	23 Oct 2020 19:02:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN ALCOHOL DEPENDENCE, PRODUCT: NALTREXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 12:52:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 12:52:52
Data point term sent to Coder	System	31 Aug 2020 19:38:52
User entered 'naltrexone'	Josie Marshall (b) (4)	31 Aug 2020 19:38:28

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User closed query 'Per DM CLR: Prophylaxis is YES. Please review this entry as there is an MH recorded that matches this medication and used within the same timeframe.Update entry on PROPHYLAXIS or provide explanation' (Site from DM).		27 Oct 2020 05:04:51
Query 'Per DM CLR: Prophylaxis is YES. Please review this entry as there is an MH recorded that matches this medication and used within the same timeframe.Update entry on PROPHYLAXIS or provide explanation' answered with 'Pt suffers from migraines, med is being used to prevent more. ' (Site from DM).	Josie Marshall (b) (4)	23 Oct 2020 19:01:40
	(b) (4)	
User opened query 'Per DM CLR: Prophylaxis is YES. Please review this entry as there is an MH recorded that matches this medication and used within the same timeframe.Update entry on PROPHYLAXIS or provide explanation' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 12:25:48
User entered 'Yes (Y)'	Josie Marshall (b) (4)	31 Aug 2020 19:38:28
	(b) (4)	

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:55:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'MIGRAINE prevention' reason for change: Data Entry Error	Josie Marshall (b) (4) (b) (4)	23 Oct 2020 19:02:47
User entered 'migraines'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:38:28

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '4.5'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:38:28



US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'mg (mg)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:38:28

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:55:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:38:28

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'once daily (QD)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:38:28

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:55:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:38:28

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Oral (ORAL)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:38:28

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:55:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:38:28

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'un UNK 2005'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:38:28

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '0'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:38:28



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Yes (Y)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:38:28

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:55:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:38:28

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:38:28

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 19:38:28

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 19:38:28

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 19:38:28

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:55:38

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 04:30:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 04:30:41
Data point term sent to Coder	System	23 Oct 2020 19:04:21
Coding entries removed.	Josie Marshall (b) (4) (b) (4)	23 Oct 2020 19:03:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 03:23:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 03:23:45
Data point term sent to Coder	System	31 Aug 2020 19:39:53
User entered 'sertraline'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:39:26

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Jan 2021 10:58:24
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' answered with 'This is correct as is.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 23:30:09
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 04:41:44
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Josie Marshall (b) (4) (b) (4)	23 Oct 2020 18:59:56
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:39:26



US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:55:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).		27 Oct 2020 05:05:09
User entered 'MIGRAINE prevention' reason for change: Data Entry Error	Josie Marshall (b) (4)	23 Oct 2020 19:03:29
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'Correct indication, being used off label.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'Correct indication, being used off label.' (Site from DM).	Josie Marshall (b) (4)	23 Oct 2020 19:00:48
	(b) (4)	
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 12:26:10
User entered 'migraines'	Josie Marshall (b) (4)	31 Aug 2020 19:39:26
	(b) (4)	

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '50'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:39:26

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'mg (mg)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:39:26

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:55:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:39:26

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:55:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'once daily (QD)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:39:26

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:55:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:39:26

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:55:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Oral (ORAL)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:39:26

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:55:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:39:26



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'un UNK 2017'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:39:26

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '0'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:39:26

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:55:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Yes (Y)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:39:26

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:55:38**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:39:26

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:55:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:39:26

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:55:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 19:39:26

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 19:39:26

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 19:39:26



US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 19:41:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 19:41:40
Data point term sent to Coder	System	31 Aug 2020 19:40:56
User entered 'rosuvastatin'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:40:09

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:55:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:40:09

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:55:38**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'high cholesterol'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:40:09

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '10'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:40:09

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'mg (mg)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:40:09

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:55:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:40:09

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:55:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'once daily (QD)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:40:09

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:55:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:40:09



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:55:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Oral (ORAL)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:40:09

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:55:38**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:40:09

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'un UNK 2017'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:40:09

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '0'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:40:09

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:55:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Yes (Y)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:40:09

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:55:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:40:09

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:55:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:40:09

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:55:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 19:40:09



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 19:40:09

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 19:40:09

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 10:26:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 10:26:45
Data point term sent to Coder	System	31 Aug 2020 19:40:57
User entered 'magnesium'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:40:46

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Yes (Y)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:40:46

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'general wellness'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:40:46

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:55:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).		27 Oct 2020 05:12:22
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'done' (Site from DM).	Josie Marshall (b) (4)	23 Oct 2020 18:47:45
User entered '250' reason for change: Data Entry Error	(b) (4)	23 Oct 2020 18:47:40
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 12:28:56
User entered '1'	Josie Marshall (b) (4)	31 Aug 2020 19:40:46

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'mg (mg)' reason for change: Data Entry Error	Josie Marshall (b) (4)	23 Oct 2020 18:47:40
User entered 'tablet (TABLET)'	Josie Marshall (b) (4)	31 Aug 2020 19:40:46

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:55:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:40:46



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'once daily (QD)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:40:46

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:55:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:40:46

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Oral (ORAL)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:40:46

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:55:38**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:40:46

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'un UNK 2005'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:40:46

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '0'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:40:46

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Yes (Y)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:40:46

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:55:38**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:40:46



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:40:46

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 19:40:46

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 19:40:46

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 19:40:46

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: UBIDECARENONE, PRODUCTSYNONYM: COQ10 [UBIDECARENONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 05:35:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 05:35:40
Data point term sent to Coder	System	31 Aug 2020 19:41:58
User entered 'coq10'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:41:20

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:55:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Yes (Y)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:41:20

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:55:38**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'general wellness'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:41:20

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:55:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).		27 Oct 2020 05:12:33
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'done' (Site from DM).	Josie Marshall (b) (4)	23 Oct 2020 18:48:28
User entered '200' reason for change: Data Entry Error	Josie Marshall (b) (4)	23 Oct 2020 18:48:23
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 12:29:30
User entered '1'	Josie Marshall (b) (4)	31 Aug 2020 19:41:20



US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'mg (mg)' reason for change: Data Entry Error	Josie Marshall (b) (4) (b) (4)	23 Oct 2020 18:48:23
User entered 'tablet (TABLET)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:41:20

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:55:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:41:20

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:55:38**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'once daily (QD)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:41:20

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:55:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:41:20

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:55:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Oral (ORAL)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:41:20

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:55:38**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:41:20

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'un UNK 2005'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:41:20

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '0'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:41:20



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:55:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Yes (Y)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:41:20

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:55:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:41:20

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:41:20

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:55:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 19:41:20

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 19:41:20

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 19:41:20

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 19:42:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 19:42:36
Data point term sent to Coder	System	31 Aug 2020 19:41:59
User entered 'zyrtec'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:41:57

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:55:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:41:57



US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:55:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'seasonal allergies'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:41:57

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '10'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:41:57

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'mg (mg)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:41:57

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:55:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:41:57

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:55:38**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'once daily (QD)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:41:57

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:55:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:41:57

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:55:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Oral (ORAL)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:41:57

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:55:38**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:41:57



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'un UNK 2010'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:41:57

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '0'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:41:57

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:55:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Yes (Y)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:41:57

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:55:38**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:41:57

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:41:57

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:55:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 19:41:57

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 19:41:57

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 19:41:57



US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: LASMIDITAN SUCCINATE, PRODUCTSYNONYM: REYVOW - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 19:43:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 19:43:39
Data point term sent to Coder	System	31 Aug 2020 19:43:01
User entered 'reyvow'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:42:37

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:55:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Yes (Y)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:42:37

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:55:38**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'migraine prevention'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:42:37

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '50'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:42:37

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'mg (mg)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:42:37

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:55:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:42:37

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:55:38**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'as needed (PRN)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:42:37

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:55:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:42:37



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:55:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Oral (ORAL)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:42:37

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:55:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:42:37

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'un UNK 2020'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:42:37

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '0'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:42:37

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:55:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Yes (Y)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:42:37

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:55:38**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:42:37

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:42:37

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:55:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 19:42:37



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 19:42:37

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 19:42:37

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:55:38

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: PROMETHAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 04:47:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 04:47:46
Data point term sent to Coder	System	23 Oct 2020 19:05:22
Coding entries removed.	Josie Marshall (b) (4) (b) (4)	23 Oct 2020 19:05:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: PROMETHAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 07:57:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 07:57:41
Data point term sent to Coder	System	31 Aug 2020 19:44:04
User entered 'promethazine'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:43:35

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:55:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User closed query 'Per DM CLR: Prophylaxis is YES. Please review this entry as there is an MH of MIGRAINE recorded that matches this medication and used within the same timeframe.Update entry on PROPHYLAXIS or provide explanation' (Site from DM).		27 Oct 2020 05:12:54
Query 'Per DM CLR: Prophylaxis is YES. Please review this entry as there is an MH of MIGRAINE recorded that matches this medication and used within the same timeframe.Update entry on PROPHYLAXIS or provide explanation' answered with 'used prophylactically ' (Site from DM).	Josie Marshall (b) (4)	23 Oct 2020 19:04:51
User opened query 'Per DM CLR: Prophylaxis is YES. Please review this entry as there is an MH of MIGRAINE recorded that matches this medication and used within the same timeframe.Update entry on PROPHYLAXIS or provide explanation' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 12:30:24
User entered 'Yes (Y)'	Josie Marshall (b) (4)	31 Aug 2020 19:43:35

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:55:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User closed query 'Per DM CLR: Indication includes Nausea, but please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. Otherwise provide clarification' (Site from DM).		27 Oct 2020 05:12:59
Query 'Per DM CLR: Indication includes Nausea, but please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. Otherwise provide clarification' answered with 'prophylactic use' (Site from DM).	Josie Marshall (b) (4)	23 Oct 2020 19:05:30
User entered 'MIGRAINE related NAUSEA prevention' reason for change: Data Entry Error	(b) (4)	23 Oct 2020 19:05:02
User opened query 'Per DM CLR: Indication includes Nausea, but please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. Otherwise provide clarification' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 12:30:15
User entered 'migraine nausea'	Josie Marshall (b) (4)	31 Aug 2020 19:43:35

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '25'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:43:35

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'mg (mg)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:43:35

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:55:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:43:35



US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:55:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'as needed (PRN)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:43:35

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:55:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:43:35

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:55:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Oral (ORAL)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:43:35

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:55:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:43:35

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'un UNK 2019'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:43:35

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '0'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:43:35

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:55:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Yes (Y)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:43:35

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:55:38**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:43:35



US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:43:35

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:55:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 19:43:35

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 19:43:35

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 19:43:35

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLOVENT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 19:46:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 19:46:41
Data point term sent to Coder	System	31 Aug 2020 19:45:08
User entered 'flovent'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:44:15

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:55:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:44:15

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:55:38**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'asthma'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:44:15

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '110'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:44:15



US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).		27 Oct 2020 05:13:11
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'corrected' (Site from DM).	Josie Marshall (b) (4)	23 Oct 2020 18:50:23
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4)	23 Oct 2020 18:50:15
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 12:30:55
User entered 'mg (mg)'	Josie Marshall (b) (4)	31 Aug 2020 19:44:15
	(b) (4)	

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:55:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:44:15

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:55:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'as needed (PRN)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:44:15

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:55:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:44:15

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:55:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:44:15

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:55:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:44:15

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'un UNK 2017'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:44:15

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '0'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:44:15



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:55:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Yes (Y)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:44:15

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:55:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:44:15

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:44:15

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:55:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 19:44:15

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 19:44:15

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 19:44:15

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 19:46:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 19:46:41
Data point term sent to Coder	System	31 Aug 2020 19:45:10
User entered 'albuterol'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:44:49

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:55:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:44:49



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:55:38**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'asthma'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:44:49

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '90'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:44:49

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).		27 Oct 2020 05:13:23
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'corrected' (Site from DM).	Josie Marshall (b) (4)	23 Oct 2020 18:50:48
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4)	23 Oct 2020 18:50:41
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 12:31:08
User entered 'mg (mg)'	Josie Marshall (b) (4)	31 Aug 2020 19:44:49
	(b) (4)	

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:55:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:44:49

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:55:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'as needed (PRN)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:44:49

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:55:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:44:49

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:55:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:44:49

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:55:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:44:49



US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:55:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'un UNK 2017'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:44:49

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '0'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:44:49

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:55:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Yes (Y)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:44:49

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:55:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:44:49

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:55:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:44:49

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:55:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 19:44:49

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 19:44:49

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 19:44:49



US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: BIOTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 19:47:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 19:47:42
Data point term sent to Coder	System	31 Aug 2020 19:46:11
User entered 'biotin'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:45:21

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:55:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:45:21

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:55:38**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'general wellness'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:45:21

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '5000'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:45:21

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).		27 Oct 2020 05:13:42
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'done' (Site from DM).	Josie Marshall (b) (4)	23 Oct 2020 18:51:06
	(b) (4)	
User entered 'ug (ug)' reason for change: Data Entry Error	Josie Marshall (b) (4)	23 Oct 2020 18:51:02
	(b) (4)	
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 12:31:29
User entered 'mg (mg)'	Josie Marshall (b) (4)	31 Aug 2020 19:45:21
	(b) (4)	

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:45:21

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:55:38**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'as needed (PRN)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:45:21

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:55:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:45:21



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:55:38**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Oral (ORAL)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:45:21

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:45:21

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:55:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'un UNK 2017'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:45:21

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '0'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:45:21

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:55:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Yes (Y)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:45:21

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:55:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:45:21

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:55:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	31 Aug 2020 19:45:21

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:55:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 19:45:21



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 19:45:21

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 19:45:21

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:02:12
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: FATTY ACID DERIVATIVES, PRODUCT: VALPROATE SODIUM, PRODUCTSYNONYM: VALPROATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 20:43:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 20:43:59
Data point term sent to Coder	System	21 Sep 2020 20:43:14
User entered 'valproate'	Josie Marshall (b) (4) (b) (4)	21 Sep 2020 20:42:23

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:55:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:02:12
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	21 Sep 2020 20:42:23

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:55:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:02:12
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'treatment of acute migraine'	Josie Marshall (b) (4)	21 Sep 2020 20:42:23

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:02:12
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '500'	Josie Marshall (b) (4)	21 Sep 2020 20:42:23

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:02:12
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'mg (mg)'	Josie Marshall (b) (4)	21 Sep 2020 20:42:23

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:55:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:02:12
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	21 Sep 2020 20:42:23



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:55:38**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:02:12
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'once (ONCE)'	Josie Marshall (b) (4)	21 Sep 2020 20:42:23

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:55:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:02:12
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	21 Sep 2020 20:42:23

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:55:38**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:02:12
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Intravenous (INTRAVENOUS)'	Josie Marshall (b) (4)	21 Sep 2020 20:42:23

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:55:38**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:02:12
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	21 Sep 2020 20:42:23

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:02:12
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '16 Sep 2020'	Josie Marshall (b) (4)	21 Sep 2020 20:42:23

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:02:12
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '0'	Josie Marshall (b) (4)	21 Sep 2020 20:42:23

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:55:38**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:02:12
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	21 Sep 2020 20:42:23

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:55:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:02:12
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '16 Sep 2020'	Josie Marshall (b) (4)	21 Sep 2020 20:42:23



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:55:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:02:12
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	21 Sep 2020 20:42:23

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:55:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:02:12
User entered empty.	System	21 Sep 2020 20:42:23

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:02:12
User entered empty.	System	21 Sep 2020 20:42:23

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:02:12
User entered empty.	System	21 Sep 2020 20:42:23

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:24
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, PRODUCT: PROMETHAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:52:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:52:48
Data point term sent to Coder	System	21 Sep 2020 20:54:31
User entered 'promethazine'	Josie Marshall (b) (4) (b) (4)	21 Sep 2020 20:53:32

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:55:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:24
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	21 Sep 2020 20:53:32

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:55:38**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:24
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'treatment of acute migraine'	Josie Marshall (b) (4) (b) (4)	21 Sep 2020 20:53:32

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:24
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '25'	Josie Marshall (b) (4)	21 Sep 2020 20:53:32



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:24
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'mg (mg)'	Josie Marshall (b) (4)	21 Sep 2020 20:53:32

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:55:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:24
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	21 Sep 2020 20:53:32

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:55:38**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:24
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'once (ONCE)'	Josie Marshall (b) (4)	21 Sep 2020 20:53:32

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:55:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:24
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	21 Sep 2020 20:53:32

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:55:38**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:24
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Oral (ORAL)'	Josie Marshall (b) (4)	21 Sep 2020 20:53:32

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:55:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:24
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	21 Sep 2020 20:53:32

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:24
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '16 Sep 2020'	Josie Marshall (b) (4)	21 Sep 2020 20:53:32

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:24
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '0'	Josie Marshall (b) (4)	21 Sep 2020 20:53:32



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:55:38**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:24
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	21 Sep 2020 20:53:32

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:55:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:24
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '16 Sep 2020'	Josie Marshall (b) (4)	21 Sep 2020 20:53:32

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:55:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:24
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	21 Sep 2020 20:53:32

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:55:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:24
User entered empty.	System	21 Sep 2020 20:53:32

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:24
User entered empty.	System	21 Sep 2020 20:53:32

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:24
User entered empty.	System	21 Sep 2020 20:53:32

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:07
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: PHENOTHIAZINES WITH PIPERAZINE STRUCTURE, PRODUCT: PROCHLORPERAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:52:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:52:48
Data point term sent to Coder	System	21 Sep 2020 20:54:32
User entered 'prochlorperazine'	Josie Marshall (b) (4) (b) (4)	21 Sep 2020 20:54:26

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:55:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:07
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	21 Sep 2020 20:54:26



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:55:38**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:07
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'treatment of acute migraine'	Josie Marshall (b) (4)	21 Sep 2020 20:54:26

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:07
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '5'	Josie Marshall (b) (4)	21 Sep 2020 20:54:26

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:07
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'mg (mg)'	Josie Marshall (b) (4)	21 Sep 2020 20:54:26

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:55:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:07
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	21 Sep 2020 20:54:26

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:55:38**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:07
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'once (ONCE)'	Josie Marshall (b) (4)	21 Sep 2020 20:54:26

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:55:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:07
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	21 Sep 2020 20:54:26

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:55:38**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:07
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Intravenous (INTRAVENOUS)'	Josie Marshall (b) (4)	21 Sep 2020 20:54:26

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:55:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:07
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	21 Sep 2020 20:54:26



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:07
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '16 Sep 2020'	Josie Marshall (b) (4)	21 Sep 2020 20:54:26

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:07
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '0'	Josie Marshall (b) (4)	21 Sep 2020 20:54:26

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:55:38**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:07
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	21 Sep 2020 20:54:26

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:55:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:07
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '16 Sep 2020'	Josie Marshall (b) (4)	21 Sep 2020 20:54:26

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:55:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:07
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	21 Sep 2020 20:54:26

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:55:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:07
User entered empty.	System	21 Sep 2020 20:54:26

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:07
User entered empty.	System	21 Sep 2020 20:54:26

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:30:07
User entered empty.	System	21 Sep 2020 20:54:26



US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:05
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:02:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:02:30
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:45:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:45:53
Data point term sent to Coder	System	21 Sep 2020 20:55:32
User entered 'normal saline ivf'	Josie Marshall (b) (4) (b) (4)	21 Sep 2020 20:55:18

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 07:55:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:05
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	21 Sep 2020 20:55:18

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 07:55:38**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:05
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'treatment of acute migraine'	Josie Marshall (b) (4)	21 Sep 2020 20:55:18

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:05
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '1000'	Josie Marshall (b) (4)	21 Sep 2020 20:55:18

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:05
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'mL (mL)'	Josie Marshall (b) (4)	21 Sep 2020 20:55:18

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 07:55:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:05
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	21 Sep 2020 20:55:18

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 07:55:38**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:05
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'once (ONCE)'	Josie Marshall (b) (4)	21 Sep 2020 20:55:18

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 07:55:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:05
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	21 Sep 2020 20:55:18



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 07:55:38**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:05
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Intravenous (INTRAVENOUS)'	Josie Marshall (b) (4)	21 Sep 2020 20:55:18

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 07:55:38**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:05
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	21 Sep 2020 20:55:18

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:05
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '16 Sep 2020'	Josie Marshall (b) (4)	21 Sep 2020 20:55:18

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:05
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '0'	Josie Marshall (b) (4)	21 Sep 2020 20:55:18

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 07:55:38**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:05
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	21 Sep 2020 20:55:18

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 07:55:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:05
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '16 Sep 2020'	Josie Marshall (b) (4)	21 Sep 2020 20:55:18

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 07:55:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:05
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	21 Sep 2020 20:55:18

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 07:55:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:05
User entered empty.	System	21 Sep 2020 20:55:18



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:05
User entered empty.	System	21 Sep 2020 20:55:18

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:05
User entered empty.	System	21 Sep 2020 20:55:18

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:10
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:19:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 21:19:40
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:33:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:33:55
Data point term sent to Coder	System	21 Sep 2020 20:56:34
User entered 'magnesium sulfate'	Josie Marshall (b) (4) (b) (4)	21 Sep 2020 20:56:01

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 07:55:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:10
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	21 Sep 2020 20:56:01

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 07:55:38**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:10
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'treatment of acute migraine'	Josie Marshall (b) (4)	21 Sep 2020 20:56:01

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:10
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'I'	Josie Marshall (b) (4)	21 Sep 2020 20:56:01

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:10
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'g (g)'	Josie Marshall (b) (4)	21 Sep 2020 20:56:01

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 07:55:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:10
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	21 Sep 2020 20:56:01



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 07:55:38**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:10
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'once (ONCE)'	Josie Marshall (b) (4)	21 Sep 2020 20:56:01

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 07:55:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:10
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	21 Sep 2020 20:56:01

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 07:55:38**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:10
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Intravenous (INTRAVENOUS)'	Josie Marshall (b) (4)	21 Sep 2020 20:56:01

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 07:55:38**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:10
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	21 Sep 2020 20:56:01

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:10
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '16 Sep 2020'	Josie Marshall (b) (4)	21 Sep 2020 20:56:01

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:10
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '0'	Josie Marshall (b) (4)	21 Sep 2020 20:56:01

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 07:55:38**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:10
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	21 Sep 2020 20:56:01

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 07:55:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:10
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '16 Sep 2020'	Josie Marshall (b) (4)	21 Sep 2020 20:56:01



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 07:55:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:10
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	21 Sep 2020 20:56:01

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 07:55:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:10
User entered empty.	System	21 Sep 2020 20:56:01

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:10
User entered empty.	System	21 Sep 2020 20:56:01

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:10
User entered empty.	System	21 Sep 2020 20:56:01

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:14
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DIPHENHYDRAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 01:33:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 01:33:47
Data point term sent to Coder	System	21 Sep 2020 20:57:35
User entered 'diphenhydramine'	Josie Marshall (b) (4) (b) (4)	21 Sep 2020 20:56:44

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 07:55:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:14
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	21 Sep 2020 20:56:44

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 07:55:38**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:14
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'treatment of acute migraine'	Josie Marshall (b) (4)	21 Sep 2020 20:56:44

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:14
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '25'	Josie Marshall (b) (4) (b) (4)	21 Sep 2020 20:56:44



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:14
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'mg (mg)'	Josie Marshall (b) (4) (b) (4)	21 Sep 2020 20:56:44

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 07:55:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:14
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	21 Sep 2020 20:56:44

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 07:55:38**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:14
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'once (ONCE)'	Josie Marshall (b) (4)	21 Sep 2020 20:56:44

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 07:55:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:14
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	21 Sep 2020 20:56:44

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 07:55:38**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:14
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Intravenous (INTRAVENOUS)'	Josie Marshall (b) (4) (b) (4)	21 Sep 2020 20:56:44

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 07:55:38**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:14
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	21 Sep 2020 20:56:44

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:14
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '16 Sep 2020'	Josie Marshall (b) (4)	21 Sep 2020 20:56:44

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:14
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '0'	Josie Marshall (b) (4)	21 Sep 2020 20:56:44



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 07:55:38**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:14
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	21 Sep 2020 20:56:44

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 07:55:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:14
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '16 Sep 2020'	Josie Marshall (b) (4)	21 Sep 2020 20:56:44

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 07:55:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:14
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4) (b) (4)	21 Sep 2020 20:56:44

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 07:55:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:14
User entered empty.	System	21 Sep 2020 20:56:44

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:14
User entered empty.	System	21 Sep 2020 20:56:44

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:14
User entered empty.	System	21 Sep 2020 20:56:44

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:39:02
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
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: DEXAMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:09:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 05:09:47
Data point term sent to Coder	System	21 Sep 2020 20:57:35
User entered 'dexamethasone'	Josie Marshall (b) (4) (b) (4)	21 Sep 2020 20:57:25

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 07:55:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:39:02
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	21 Sep 2020 20:57:25



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 07:55:38**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:39:02
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'treatment of acute migraine'	Josie Marshall (b) (4)	21 Sep 2020 20:57:25

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:39:02
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '10'	Josie Marshall (b) (4)	21 Sep 2020 20:57:25

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:39:02
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'mg (mg)'	Josie Marshall (b) (4)	21 Sep 2020 20:57:25

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 07:55:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:39:02
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	21 Sep 2020 20:57:25

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 07:55:38**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:39:02
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'once (ONCE)'	Josie Marshall (b) (4)	21 Sep 2020 20:57:25

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 07:55:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:39:02
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	21 Sep 2020 20:57:25

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 07:55:38**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:39:02
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Intravenous (INTRAVENOUS)'	Josie Marshall (b) (4)	21 Sep 2020 20:57:25

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 07:55:38**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:39:02
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	21 Sep 2020 20:57:25



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:39:02
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '16 Sep 2020'	Josie Marshall (b) (4)	21 Sep 2020 20:57:25

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:39:02
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '0'	Josie Marshall (b) (4)	21 Sep 2020 20:57:25

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 07:55:38**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:39:02
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	21 Sep 2020 20:57:25

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 07:55:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:39:02
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '16 Sep 2020'	Josie Marshall (b) (4)	21 Sep 2020 20:57:25

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 07:55:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:39:02
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	21 Sep 2020 20:57:25

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 07:55:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:39:02
User entered empty.	System	21 Sep 2020 20:57:25

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:39:02
User entered empty.	System	21 Sep 2020 20:57:25

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:39:02
User entered empty.	System	21 Sep 2020 20:57:25



US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: PHENOTHIAZINES WITH PIPERAZINE STRUCTURE, PRODUCT: PROCHLORPERAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 12:03:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 12:03:42
Data point term sent to Coder	System	24 Sep 2020 16:14:36
User entered 'compazine'	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:13:38

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 07:55:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	24 Sep 2020 16:13:38

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 07:55:38**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'treatment of migraine'	Josie Marshall (b) (4)	24 Sep 2020 16:13:38

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '5'	Josie Marshall (b) (4)	24 Sep 2020 16:13:38

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'mg (mg)'	Josie Marshall (b) (4)	24 Sep 2020 16:13:38

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 07:55:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	24 Sep 2020 16:13:38

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 07:55:38**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'once (ONCE)'	Josie Marshall (b) (4)	24 Sep 2020 16:13:38

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 07:55:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	24 Sep 2020 16:13:38



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 07:55:38**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Intravenous (INTRAVENOUS)'	Josie Marshall (b) (4)	24 Sep 2020 16:13:38

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 07:55:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	24 Sep 2020 16:13:38

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '22 Sep 2020'	Josie Marshall (b) (4)	24 Sep 2020 16:13:38

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '0'	Josie Marshall (b) (4)	24 Sep 2020 16:13:38

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 07:55:38**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	24 Sep 2020 16:13:38

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 07:55:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '22 Sep 2020'	Josie Marshall (b) (4)	24 Sep 2020 16:13:38

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 07:55:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:25
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	24 Sep 2020 16:13:38

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 07:55:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:25
User entered empty.	System	24 Sep 2020 16:13:38



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:25
User entered empty.	System	24 Sep 2020 16:13:38

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:35:25
User entered empty.	System	24 Sep 2020 16:13:38

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 07:55:38

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:26
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 17:32:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 17:32:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DIPHENHYDRAMINE;PARACETAMOL;PHENY LPROPANOLAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE;PARACETAMOL;PHENY LPROPANOLAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 09:18:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 09:18:45
Data point term sent to Coder	System	24 Sep 2020 16:14:37
User entered 'benadryl'	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:14:17

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 07:55:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:26
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	24 Sep 2020 16:14:17

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 07:55:38**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:26
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'treatment of migraine'	Josie Marshall (b) (4)	24 Sep 2020 16:14:17

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:26
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '25'	Josie Marshall (b) (4)	24 Sep 2020 16:14:17

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:26
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'mg (mg)'	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:14:17

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 07:55:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:26
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	24 Sep 2020 16:14:17



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 07:55:38**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:26
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'once (ONCE)'	Josie Marshall (b) (4)	24 Sep 2020 16:14:17

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 07:55:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:26
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:14:17

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 07:55:38**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:26
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Intravenous (INTRAVENOUS)'	Josie Marshall (b) (4)	24 Sep 2020 16:14:17

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 07:55:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:26
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	24 Sep 2020 16:14:17

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:26
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '22 Sep 2020'	Josie Marshall (b) (4)	24 Sep 2020 16:14:17

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:26
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '0'	Josie Marshall (b) (4)	24 Sep 2020 16:14:17

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 07:55:38**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:26
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	24 Sep 2020 16:14:17

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 07:55:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:26
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '22 Sep 2020'	Josie Marshall (b) (4)	24 Sep 2020 16:14:17



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 07:55:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:26
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	24 Sep 2020 16:14:17

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 07:55:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:26
User entered empty.	System	24 Sep 2020 16:14:17

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:26
User entered empty.	System	24 Sep 2020 16:14:17

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:26
User entered empty.	System	24 Sep 2020 16:14:17

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 07:55:38

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:32
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:14:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:14:30
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 13:14:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 13:14:41
Data point term sent to Coder	System	24 Sep 2020 16:15:41
User entered 'magnesium sulfate'	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:15:15

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 07:55:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	24 Sep 2020 16:15:15

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 07:55:38**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'treatment of migraine'	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:15:15

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'I'	Josie Marshall (b) (4)	24 Sep 2020 16:15:15



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'g (g)'	Josie Marshall (b) (4)	24 Sep 2020 16:15:15

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 07:55:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	24 Sep 2020 16:15:15

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 07:55:38**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'once (ONCE)'	Josie Marshall (b) (4)	24 Sep 2020 16:15:15

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 07:55:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	24 Sep 2020 16:15:15

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 07:55:38**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Intravenous (INTRAVENOUS)'	Josie Marshall (b) (4)	24 Sep 2020 16:15:15

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 07:55:38**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	24 Sep 2020 16:15:15

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '22 Sep 2020'	Josie Marshall (b) (4)	24 Sep 2020 16:15:15

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '0'	Josie Marshall (b) (4)	24 Sep 2020 16:15:15



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 07:55:38**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	24 Sep 2020 16:15:15

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 07:55:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '22 Sep 2020'	Josie Marshall (b) (4)	24 Sep 2020 16:15:15

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 07:55:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:32
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	24 Sep 2020 16:15:15

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 07:55:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:32
User entered empty.	System	24 Sep 2020 16:15:15

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:32
User entered empty.	System	24 Sep 2020 16:15:15

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:32
User entered empty.	System	24 Sep 2020 16:15:15

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:34
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:02:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 17:02:18
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: NORMAL SALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 10:15:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 10:15:57
Data point term sent to Coder	System	24 Sep 2020 16:16:47
User entered 'normal saline ivf'	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:16:25

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 07:55:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:34
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	24 Sep 2020 16:16:25



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 07:55:38**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:34
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'treatment of migraine'	Josie Marshall (b) (4)	24 Sep 2020 16:16:25

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:34
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '1000'	Josie Marshall (b) (4)	24 Sep 2020 16:16:25

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:34
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'mL (mL)'	Josie Marshall (b) (4)	24 Sep 2020 16:16:25

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 07:55:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:34
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	24 Sep 2020 16:16:25

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 07:55:38**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:34
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'once (ONCE)'	Josie Marshall (b) (4)	24 Sep 2020 16:16:25

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 07:55:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:34
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	24 Sep 2020 16:16:25

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 07:55:38**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:34
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Intravenous (INTRAVENOUS)'	Josie Marshall (b) (4)	24 Sep 2020 16:16:25

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 07:55:38**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:34
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	24 Sep 2020 16:16:25



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:34
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '22 Sep 2020'	Josie Marshall (b) (4)	24 Sep 2020 16:16:25

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:34
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '0'	Josie Marshall (b) (4)	24 Sep 2020 16:16:25

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 07:55:38**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:34
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	24 Sep 2020 16:16:25

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 07:55:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:34
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '22 Sep 2020'	Josie Marshall (b) (4)	24 Sep 2020 16:16:25

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 07:55:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:34
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	24 Sep 2020 16:16:25

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 07:55:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:34
User entered empty.	System	24 Sep 2020 16:16:25

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:34
User entered empty.	System	24 Sep 2020 16:16:25

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:34
User entered empty.	System	24 Sep 2020 16:16:25



US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:04
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 08:26:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 08:26:40
Data point term sent to Coder	System	24 Sep 2020 16:17:49
User entered 'lorazepam'	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:17:01

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 07:55:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:04
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	24 Sep 2020 16:17:01

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 07:55:38**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:04
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'treatment of migraine'	Josie Marshall (b) (4)	24 Sep 2020 16:17:01

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:04
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '0.5'	Josie Marshall (b) (4)	24 Sep 2020 16:17:01

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:04
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'mg (mg)'	Josie Marshall (b) (4)	24 Sep 2020 16:17:01

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 07:55:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:04
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	24 Sep 2020 16:17:01

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 07:55:38**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:04
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'once (ONCE)'	Josie Marshall (b) (4)	24 Sep 2020 16:17:01

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 07:55:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:04
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	24 Sep 2020 16:17:01



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 07:55:38**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:04
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Intravenous (INTRAVENOUS)'	Josie Marshall (b) (4)	24 Sep 2020 16:17:01

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 07:55:38**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:04
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	24 Sep 2020 16:17:01

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:04
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '22 Sep 2020'	Josie Marshall (b) (4)	24 Sep 2020 16:17:01

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:04
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '0'	Josie Marshall (b) (4)	24 Sep 2020 16:17:01

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 07:55:38**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:04
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	24 Sep 2020 16:17:01

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 07:55:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:04
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '22 Sep 2020'	Josie Marshall (b) (4)	24 Sep 2020 16:17:01

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 07:55:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:04
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	24 Sep 2020 16:17:01

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 07:55:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:04
User entered empty.	System	24 Sep 2020 16:17:01



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:04
User entered empty.	System	24 Sep 2020 16:17:01

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:12:04
User entered empty.	System	24 Sep 2020 16:17:01

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 07:55:38

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:45
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC TROMETHAMINE, PRODUCTSYNONYM: TORADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 08:52:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 08:52:43
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 20:44:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 20:44:36
Data point term sent to Coder	System	24 Sep 2020 16:17:49
User entered 'toradol'	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:17:39

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 07:55:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:45
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	24 Sep 2020 16:17:39

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 07:55:38**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:45
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'treatment of migraine'	Josie Marshall (b) (4)	24 Sep 2020 16:17:39

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:45
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '30'	Josie Marshall (b) (4)	24 Sep 2020 16:17:39

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:45
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'mg (mg)'	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:17:39

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 07:55:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:45
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	24 Sep 2020 16:17:39



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 07:55:38**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:45
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'as needed (PRN)'	Josie Marshall (b) (4)	24 Sep 2020 16:17:39

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 07:55:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:45
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	24 Sep 2020 16:17:39

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 07:55:38**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:45
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Intravenous (INTRAVENOUS)'	Josie Marshall (b) (4)	24 Sep 2020 16:17:39

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 07:55:38**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:45
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:17:39

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:45
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '22 Sep 2020'	Josie Marshall (b) (4)	24 Sep 2020 16:17:39

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:45
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '0'	Josie Marshall (b) (4)	24 Sep 2020 16:17:39

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 07:55:38**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:45
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	24 Sep 2020 16:17:39

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 07:55:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:45
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '23 Sep 2020'	Josie Marshall (b) (4)	24 Sep 2020 16:17:39



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 07:55:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:45
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	24 Sep 2020 16:17:39

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 07:55:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:45
User entered empty.	System	24 Sep 2020 16:17:39

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:45
User entered empty.	System	24 Sep 2020 16:17:39

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:25:45
User entered empty.	System	24 Sep 2020 16:17:39

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 07:55:38

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:37:42
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening MUSCLE SPASMS - LOW BACK should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Jan 2021 10:58:13
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening MUSCLE SPASMS - LOW BACK should be recorded, and update con med indication or provide clarification.	(b) (4), (b) (6)	05 Jan 2021 23:39:35
' answered with 'Not worsening. Just taken for one day in correlation with migraines.' (Site from DM).		
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening MUSCLE SPASMS - LOW BACK should be recorded, and update con med indication or provide clarification.	(b) (4), (b) (6)	04 Jan 2021 04:40:28
' (Site from DM).		
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 20:10:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Nov 2020 20:10:29
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
Data point term sent to Coder	System	03 Nov 2020 17:01:19
Coding entries removed.	Josie Marshall (b) (4) (b) (4)	03 Nov 2020 17:00:27

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 16:20:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 16:20:48
Data point term sent to Coder	System	24 Sep 2020 16:19:52
User entered 'cyclobenzaprine'	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:18:54

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 07:55:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:37:42
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	24 Sep 2020 16:18:54

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 07:55:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:37:42
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'MUSCLE SPASMS - low back'	Josie Marshall (b) (4)	03 Nov 2020 17:00:27
reason for change: Data Entry Error	(b) (4)	
User entered 'muscle spasms'	Josie Marshall (b) (4)	24 Sep 2020 16:18:54
	(b) (4)	



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:37:42
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '5'	Josie Marshall (b) (4)	24 Sep 2020 16:18:54

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:37:42
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'mg (mg)'	Josie Marshall (b) (4)	24 Sep 2020 16:18:54

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 07:55:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:37:42
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	24 Sep 2020 16:18:54

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 07:55:38**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:37:42
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'as needed (PRN)'	Josie Marshall (b) (4)	24 Sep 2020 16:18:54

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 07:55:38

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:37:42
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	24 Sep 2020 16:18:54

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 07:55:38**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:37:42
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Oral (ORAL)'	Josie Marshall (b) (4)	24 Sep 2020 16:18:54

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 07:55:38**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:37:42
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	24 Sep 2020 16:18:54

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:37:42
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '23 Sep 2020'	Josie Marshall (b) (4)	24 Sep 2020 16:18:54



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:37:42
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '0'	Josie Marshall (b) (4)	24 Sep 2020 16:18:54

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 07:55:38**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:37:42
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	24 Sep 2020 16:18:54

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 07:55:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:37:42
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '23 Sep 2020'	Josie Marshall (b) (4)	24 Sep 2020 16:18:54

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 07:55:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:37:42
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	24 Sep 2020 16:18:54

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 07:55:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:37:42
User entered empty.	System	24 Sep 2020 16:18:54

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:37:42
User entered empty.	System	24 Sep 2020 16:18:54

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:37:42
User entered empty.	System	24 Sep 2020 16:18:54

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:43:52
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 16:21:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 16:21:52
Data point term sent to Coder	System	24 Sep 2020 16:20:56
User entered 'acetaminophen'	Josie Marshall (b) (4) (b) (4)	24 Sep 2020 16:20:27



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 07:55:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:43:52
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	24 Sep 2020 16:20:27

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 07:55:38**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:43:52
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'treatment of migraine'	Josie Marshall (b) (4)	24 Sep 2020 16:20:27

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:43:52
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '1000'	Josie Marshall (b) (4)	24 Sep 2020 16:20:27

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:43:52
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'mg (mg)'	Josie Marshall (b) (4)	24 Sep 2020 16:20:27

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 07:55:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:43:52
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	24 Sep 2020 16:20:27

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 07:55:38**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:43:52
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'as needed (PRN)'	Josie Marshall (b) (4)	24 Sep 2020 16:20:27

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 07:55:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:43:52
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	24 Sep 2020 16:20:27

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 07:55:38**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:43:52
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Oral (ORAL)'	Josie Marshall (b) (4)	24 Sep 2020 16:20:27



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 07:55:38**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:43:52
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Josie Marshall (b) (4)	24 Sep 2020 16:20:27

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:43:52
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '22 Sep 2020'	Josie Marshall (b) (4)	24 Sep 2020 16:20:27

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:43:52
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '0'	Josie Marshall (b) (4)	24 Sep 2020 16:20:27

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 07:55:38**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:43:52
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	24 Sep 2020 16:20:27

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 07:55:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:43:52
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '23 Sep 2020'	Josie Marshall (b) (4)	24 Sep 2020 16:20:27

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 07:55:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:43:52
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Josie Marshall (b) (4)	24 Sep 2020 16:20:27

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 07:55:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:43:52
User entered empty.	System	24 Sep 2020 16:20:27

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:43:52
User entered empty.	System	24 Sep 2020 16:20:27



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:43:52
User entered empty.	System	24 Sep 2020 16:20:27

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:30:17
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:19:53
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) (b) (4)	19 Oct 2020 19:31:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 19:31:30
Data point term sent to Coder	System	19 Oct 2020 19:30:52
User entered 'Influenza Vaccine'	Patrisha Adkins (b) (4) (b) (4)	19 Oct 2020 19:30:45

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 07:55:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:30:17
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Yes (Y)'	Patrishia Adkins (b) (4)	19 Oct 2020 19:30:45

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 07:55:38**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:30:17
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Flu prophylaxis'	Patrishia Adkins (b) (4)	19 Oct 2020 19:30:45

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:30:17
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '0.5'	Patrishia Adkins (b) (4)	19 Oct 2020 19:30:45

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:30:17
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'mL (mL)'	Patrishia Adkins (b) (4)	19 Oct 2020 19:30:45

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 07:55:38**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:30:17
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Patrishia Adkins (b) (4)	19 Oct 2020 19:30:45

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 07:55:38**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:30:17
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'once (ONCE)'	Patrishia Adkins (b) (4)	19 Oct 2020 19:30:45



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 07:55:38**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:30:17
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Patrishia Adkins (b) (4)	19 Oct 2020 19:30:45

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 07:55:38**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:30:17
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'Intramuscular (INTRAMUSCULAR)'	Patrishia Adkins (b) (4)	19 Oct 2020 19:30:45

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 07:55:38**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:30:17
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered empty.	Patrishia Adkins (b) (4)	19 Oct 2020 19:30:45

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:30:17
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '12 Oct 2020'	Patrishia Adkins (b) (4)	19 Oct 2020 19:30:45

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:30:17
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '0'	Patrishia Adkins (b) (4)	19 Oct 2020 19:30:45

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 07:55:38**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:30:17
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Patrishia Adkins (b) (4)	19 Oct 2020 19:30:45

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 07:55:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:30:17
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered '12 Oct 2020'	Patrishia Adkins (b) (4)	19 Oct 2020 19:30:45

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 07:55:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:30:17
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:19:53
User entered 'No (N)'	Patrishia Adkins (b) (4)	19 Oct 2020 19:30:45



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 07:55:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:30:17
User entered empty.	System	19 Oct 2020 19:30:45

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:30:17
User entered empty.	System	19 Oct 2020 19:30:45

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 16:30:17
User entered empty.	System	19 Oct 2020 19:30:45

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 07:55:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: DECONGESTANTS AND ANTIALLERGICS, ATC: OTHER ANTIALLERGICS, PRODUCT: KETOTIFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	25 Nov 2020 23:00:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 23:00:59
Data point term sent to Coder	System	25 Nov 2020 17:39:22
User entered 'Ketotifen'	Patrishia Adkins (b) (4) (b) (4)	25 Nov 2020 17:38:53

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 07:55:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered 'No (N)'	Patrishia Adkins (b) (4)	25 Nov 2020 17:38:53
	(b) (4)	

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 07:55:38**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered 'Seasonal allergy exacerbation'	(b) (4) Patrishia Adkins (b) (4)	25 Nov 2020 17:38:53
	(b) (4)	

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered '1'	Patrishia Adkins (b) (4)	25 Nov 2020 17:38:53
	(b) (4)	

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered 'Other (OTHER)'	Patrishia Adkins (b) (4)	25 Nov 2020 17:38:53
	(b) (4)	



US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 07:55:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered 'gtt'	Patrishia Adkins (b) (4)	25 Nov 2020 17:38:53
	(b) (4)	

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 07:55:38**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered 'once daily (QD)'	Patrishia Adkins (b) (4)	25 Nov 2020 17:38:53
	(b) (4)	

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 07:55:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered empty.	Patrishia Adkins (b) (4)	25 Nov 2020 17:38:53
	(b) (4)	

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 10 Jun 2021 07:55:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
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)	26 Feb 2021 05:03:09
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'eye drops' (Site from DM).	Suzanne Fiorillo (b) (4) (b) (4)	25 Feb 2021 01:01:44
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)	21 Jan 2021 19:17:30
User entered 'Intraocular (INTRAOCULAR)'	Patrishia Adkins (b) (4) (b) (4)	25 Nov 2020 17:38:53

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 07:55:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered empty.	Patrishia Adkins (b) (4)	25 Nov 2020 17:38:53
	(b) (4)	

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered '15 Oct 2020'	Patrishia Adkins (b) (4)	25 Nov 2020 17:38:53
	(b) (4)	

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered '0'	Patrishia Adkins (b) (4)	25 Nov 2020 17:38:53
	(b) (4)	

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 07:55:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered 'Yes (Y)'	Patrishia Adkins (b) (4)	25 Nov 2020 17:38:53
	(b) (4)	



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 07:55:38**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered empty.	Patrishia Adkins (b) (4)	25 Nov 2020 17:38:53
	(b) (4)	

US3502045

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 07:55:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered 'No (N)'	Patrisha Adkins (b) (4)	25 Nov 2020 17:38:53
	(b) (4)	

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 07:55:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Nov 2020 17:38:53

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Nov 2020 17:38:53

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Nov 2020 17:38:53

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 07:55:38

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 11:42:44
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 11:42:44
Data point term sent to Coder Coding entries removed.	System Suzanne Fiorillo (b) (4)	04 Mar 2021 22:02:05 04 Mar 2021 22:01:22
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Nov 2020 07:25:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Nov 2020 07:25:08
Data point term sent to Coder User entered 'Flonase'	System Patrisha Adkins (b) (4)	25 Nov 2020 17:41:27 25 Nov 2020 17:41:03

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 07:55:38**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered 'No (N)'	Patrishia Adkins (b) (4)	25 Nov 2020 17:41:03
	(b) (4)	

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 07:55:38**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered 'Seasonal allergy exacerbation'	(b) (4) Patrisha Adkins (b) (4)	25 Nov 2020 17:41:03
	(b) (4)	



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 07:55:38**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered '200'	Patrisha Adkins (b) (4)	25 Nov 2020 17:41:03
	(b) (4)	

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 07:55:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User closed query 'Per CDM: Kindly consider selecting "ug" from the dropdown available in dose unit. Please update, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 12:45:27
Query 'Per CDM: Kindly consider selecting "ug" from the dropdown available in dose unit. Please update, else clarify.' answered with 'Done' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 00:37:04
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Dec 2020 00:36:58
User opened query 'Per CDM: Kindly consider selecting "ug" from the dropdown available in dose unit. Please update, else clarify.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 11:45:02
User entered 'Other (OTHER)'	Patrishia Adkins (b) (4) (b) (4)	25 Nov 2020 17:41:03

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 07:55:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	02 Dec 2020 00:36:58
User entered 'mcg'	Patrishia Adkins (b) (4) (b) (4)	25 Nov 2020 17:41:03

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 07:55:38**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered 'as needed (PRN)'	Patrishia Adkins (b) (4)	25 Nov 2020 17:41:03
	(b) (4)	

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 07:55:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered empty.	Patrishia Adkins (b) (4)	25 Nov 2020 17:41:03
	(b) (4)	

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 07:55:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
User closed query 'Per DM CLR RQ: 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)	09 Mar 2021 10:09:29
Query 'Per DM CLR RQ: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'nasal??' (Site from DM).	Suzanne Fiorillo (b) (4) (b) (4)	04 Mar 2021 22:01:33
User entered 'Nasal (NASAL)' reason for change: Data Entry Error	Suzanne Fiorillo (b) (4) (b) (4)	04 Mar 2021 22:01:22
User opened query 'Per DM CLR RQ: 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)	04 Mar 2021 03:05:05
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) (6)	04 Mar 2021 03:05:05
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'inhaled??' (Site from DM).	Suzanne Fiorillo (b) (4) (b) (4)	25 Feb 2021 01:02:40
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)	21 Jan 2021 19:17:18
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Patrishia Adkins (b) (4) (b) (4)	25 Nov 2020 17:41:03

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 07:55:38**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered empty.	Patrishia Adkins (b) (4)	25 Nov 2020 17:41:03
	(b) (4)	

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered '15 Oct 2020'	Patrisha Adkins (b) (4)	25 Nov 2020 17:41:03
	(b) (4)	



**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 07:55:38**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered '0'	Patrishia Adkins (b) (4)	25 Nov 2020 17:41:03
	(b) (4)	

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 07:55:38**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered 'Yes (Y)'	Patrishia Adkins (b) (4)	25 Nov 2020 17:41:03
	(b) (4)	

US3502045

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 10 Jun 2021 07:55:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered empty.	Patrishia Adkins (b) (4)	25 Nov 2020 17:41:03
	(b) (4)	

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 07:55:38**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	19 Mar 2021 19:39:04
	(b) (4)	
User entered 'No (N)'	Patrishia Adkins (b) (4)	25 Nov 2020 17:41:03
	(b) (4)	

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 07:55:38**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Nov 2020 17:41:03

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Nov 2020 17:41:03

**US3502045**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 10 Jun 2021 07:55:38**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Nov 2020 17:41:03

US3502045

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 07:55:38

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:20:32
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 22:04:18



US3502045

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 07:55:38

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
	(b) (4)	
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Dec 2020 22:06:07
User entered '22 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Dec 2020 22:06:07
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Dec 2020 22:04:53
User entered ' 2020' (non-conformant).	(b) (4), (b) (6)	07 Dec 2020 22:04:53

**US3502045**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'MRI of brain'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 22:04:53

US3502045

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 07:55:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 22:04:53

US3502045

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 07:55:38

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 22:04:53

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:13:00
Reviewed for Safety.		25 Sep 2020 14:55:03
User entered 'USA-US080-2020-MRNA-1273-P301000001'	System	25 Sep 2020 14:54:33

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:13:00
User entered 'Yes (Y)'	System	25 Sep 2020 14:54:33

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:13:00
User entered 'No (N)'	System	25 Sep 2020 14:54:33

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:13:00
User entered 'No (N)'	System	25 Sep 2020 14:54:33



**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:13:00
User entered 'Yes (Y)'	System	25 Sep 2020 14:54:33

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:13:00
User entered 'No (N)'	System	25 Sep 2020 14:54:33

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:13:00
User entered 'No (N)'	System	25 Sep 2020 14:54:33

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:13:00
User entered 'No (N)'	System	25 Sep 2020 14:54:33

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:13:00
User entered 'Thomas'	System	25 Sep 2020 14:54:33

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:13:00
User entered 'Campbell'	System	25 Sep 2020 14:54:33

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:49:43
User entered '12401 E. 17th Ave 3rd Floor'	Josie Marshall (b) (4) (b) (4)	03 Nov 2020 17:37:02

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:49:43
User entered 'Aurora'	Josie Marshall (b) (4) (b) (4)	03 Nov 2020 17:37:02



**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:13:00
User entered 'CO'	System	25 Sep 2020 14:54:33

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:49:43
User entered '80045'	Josie Marshall (b) (4) (b) (4)	03 Nov 2020 17:37:02

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:13:00
User entered 'US'	System	25 Sep 2020 14:55:13

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '2'	(b) (4)	26 Oct 2020 18:16:27
User entered '1'	System	25 Sep 2020 14:55:13

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:13:00
Reviewed for Safety.		25 Sep 2020 14:55:03
User entered 'USA-US080-2020-MRNA-1273-P301000001'	System	25 Sep 2020 14:54:33

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:13:00
User entered 'Yes (Y)'	System	25 Sep 2020 14:54:33

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:13:00
User entered 'No (N)'	System	25 Sep 2020 14:54:33

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:13:00
User entered 'No (N)'	System	25 Sep 2020 14:54:33



**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:13:00
User entered 'Yes (Y)'	System	25 Sep 2020 14:54:33

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:13:00
User entered 'No (N)'	System	25 Sep 2020 14:54:33

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:13:00
User entered 'No (N)'	System	25 Sep 2020 14:54:33

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:13:00
User entered 'No (N)'	System	25 Sep 2020 14:54:33

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:13:00
User entered 'Thomas'	System	25 Sep 2020 14:54:33

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:13:00
User entered 'Campbell'	System	25 Sep 2020 14:54:33

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:49:43
User entered '12401 E. 17th Ave 3rd Floor'	Josie Marshall (b) (4) (b) (4)	03 Nov 2020 17:37:02

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:49:43
User entered 'Aurora'	Josie Marshall (b) (4) (b) (4)	03 Nov 2020 17:37:02



**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:13:00
User entered 'CO'	System	25 Sep 2020 14:54:33

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:49:43
User entered '80045'	Josie Marshall (b) (4) (b) (4)	03 Nov 2020 17:37:02

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:13:00
User entered 'US'	System	25 Sep 2020 14:55:13

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '2'	(b) (4)	26 Oct 2020 18:16:27
User entered '1'	System	25 Sep 2020 14:55:13

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 07:55:38**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:13:00
User entered '25/Sep/2020 14:55'	System	25 Sep 2020 14:55:13

US3502045

Folder: SAE USA-US080-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 07:55:38

**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 15:13:50
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:13:00
User entered 'I'		25 Sep 2020 14:55:13

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4)	03 Nov 2020 17:13:00
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 14:55:03
User entered 'USA-US080-2020-MRNA-1273-P301000001'	System	25 Sep 2020 14:54:33

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:13:00
User entered 'Yes (Y)'	System	25 Sep 2020 14:54:33



**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:13:00
User entered 'No (N)'	System	25 Sep 2020 14:54:33

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:13:00
User entered 'No (N)'	System	25 Sep 2020 14:54:33

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:13:00
User entered 'Yes (Y)'	System	25 Sep 2020 14:54:33

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:13:00
User entered 'No (N)'	System	25 Sep 2020 14:54:33

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:13:00
User entered 'No (N)'	System	25 Sep 2020 14:54:33

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:13:00
User entered 'No (N)'	System	25 Sep 2020 14:54:33

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:13:00
User entered 'Thomas'	System	25 Sep 2020 14:54:33

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:13:00
User entered 'Campbell'	System	25 Sep 2020 14:54:33



**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:49:43
User entered '12401 E. 17th Ave 3rd Floor'	Josie Marshall (b) (4) (b) (4)	03 Nov 2020 17:37:02

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:49:43
User entered 'Aurora'	Josie Marshall (b) (4) (b) (4)	03 Nov 2020 17:37:02

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:13:00
User entered 'CO'	System	25 Sep 2020 14:54:33

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:49:43
User entered '80045'	Josie Marshall (b) (4) (b) (4)	03 Nov 2020 17:37:02

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:13:00
User entered 'US'	System	25 Sep 2020 14:55:13

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:55:38**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
User entered '2'	(b) (4)	26 Oct 2020 18:16:27
User entered '1'	System	25 Sep 2020 14:55:13

**US3502045**

**Folder: SAE USA-US080-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 07:55:38**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thomas Campbell (b) (4)	16 Feb 2021 15:13:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:13:00
User entered '26/Oct/2020 14:16'	System	26 Oct 2020 18:16:27

US3502045

Folder: SAE USA-US080-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 07:55:38

**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 15:13:50
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:13:00
User entered 'I'		26 Oct 2020 18:16:27