

US3062048 (Prod: Alliance for Multispecialty Research, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:56:40

All time stamps listed in this document are displayed in GMT

US3062048

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 20:20:52

Generated On: 09 Jun 2021 14:56:40

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Participant ID

US3062048

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

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US3062048

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 15:18:06

Generated On: 09 Jun 2021 14:56:40

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 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	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 15:17:48

Generated On: 09 Jun 2021 14:56:40

Date of Birth (MMM yyyy)	(b) (6) 1949
Age	70
Age Units	YEARS
Age (Derived)	70
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 15:17:48

Generated On: 09 Jun 2021 14:56:40

Date of Informed Consent (*dd MMM yyyy*) 3 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input checked="" type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input type="radio"/>
Amendment 4	<input type="radio"/>
Amendment 5	<input type="radio"/>

Was participant enrolled in the study?

Yes	<input checked="" type="radio"/>
No	<input type="radio"/>

If No, indicate reason for screen fail

Withdrew Consent	<input type="radio"/>
Inclusion/Exclusion	<input type="radio"/>
Cohort Full	<input type="radio"/>
Other	<input type="radio"/>

If reason for screen fail is Other, specify \_\_\_\_\_

Was this participant screened previously?

Yes	<input type="radio"/>
No	<input checked="" type="radio"/>

If Yes, previous participant number \_\_\_\_\_

Enrollment Trigger 1

US3062048

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 15:17:48

Generated On: 09 Jun 2021 14:56:40

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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) 15 Feb 2021 15:18:06

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Were any significant conditions reported?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 31 Mar 2021 20:53:53

Generated On: 09 Jun 2021 14:56:40

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3062048

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 31 Mar 2021 20:53:53

Generated On: 09 Jun 2021 14:56:40

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	28 APR 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3062048

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 31 Mar 2021 20:53:53

Generated On: 09 Jun 2021 14:56:40

Condition	SCIATIA, LEFT
Start date (dd MMM yyyy)	UN UNK 1964
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 1964
Start Year (derived)	1964
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3062048

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 31 Mar 2021 20:53:53

Generated On: 09 Jun 2021 14:56:40

Condition	LOW BACK PAIN
Start date (dd MMM yyyy)	UN UNK 1964
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 1964
Start Year (derived)	1964
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3062048

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 31 Mar 2021 20:53:53

Generated On: 09 Jun 2021 14:56:40

Condition	PHYSICAL THERAPY
Start date (dd MMM yyyy)	12 JUN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	20 JUN 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUN 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 15:18:06

Generated On: 09 Jun 2021 14:56:40

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 AUG 2020
Time of assessment (00:00-23:59)	11:36 (24 HR)
Vital Signs Date and Time (derived)	03 AUG 2020 11:36
Height (xxx.x)	177.0 cm
Weight (xxx.x)	96.8 kg
BMI (xxx.x)	30.89789 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	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) 15 Feb 2021 15:18:06

Generated On: 09 Jun 2021 14:56:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 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: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 15:18:06

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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** True

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 15:18:06

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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)	False
<b>Other</b>	False
<b>Specify</b>	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 15:18:06

Generated On: 09 Jun 2021 14:56:40

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 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) 15 Feb 2021 15:18:06

Generated On: 09 Jun 2021 14:56:40

What was the date of randomization? (dd MMM yyyy) 03 AUG 2020

What was the participant's randomization number? 184428

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 15:18:06

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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) 15 Feb 2021 15:18:06

Generated On: 09 Jun 2021 14:56:40

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)	3 AUG 2020
Time of assessment (00:00-23:59)	11:36 (24 HR)
Vital Signs Date and Time (derived)	3 AUG 2020 11:36
Temperature (xxx.x)	96.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 15:18:06

Generated On: 09 Jun 2021 14:56:40

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)	3 AUG 2020
Time of assessment (00:00-23:59)	13:43 (24 HR)
Vital Signs Date and Time (derived)	3 AUG 2020 13:43
Temperature (xxx.x)	96.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 15:18:06

Generated On: 09 Jun 2021 14:56:40

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 15:18:06

Generated On: 09 Jun 2021 14:56:40

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) 3 AUG 2020

What was the treatment time? (00:00-23:59) 13:11 (24 HR)

Treatment Date and Time (derived) 3 AUG 2020 13:11

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) 15 Feb 2021 15:18:06

Generated On: 09 Jun 2021 14:56:40

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

Collection date (dd MMM yyyy)	3 AUG 2020
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Collection time (00:00-23:59)	12:21 (24 HR)
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Collection date and time (derived)	3 AUG 2020 12:21
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US3062048

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 15:18:06

Generated On: 09 Jun 2021 14:56:40

Collection date (dd MMM yyyy)			3 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:24	3 AUG 2020 12:24
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:18:06

Generated On: 09 Jun 2021 14:56:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:56:40

**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

96.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 AUG 2020 13:48

PC Open Date & Time

03 AUG 2020 13:31

PC Close Date & Time

03 AUG 2020 16:01

US3062048

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:56:40

**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 95.6 °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	03 AUG 2020 20:55
PC Open Date & Time	03 AUG 2020 16:56
PC Close Date & Time	04 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 21:02

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:56:40

**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

95.7 °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

05 AUG 2020 20:20

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3062048

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 19:19

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:56:40

**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

07 AUG 2020 21:09

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3062048

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:56:40

**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

98.6 °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

08 AUG 2020 19:50

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3062048

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.1 °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

09 AUG 2020 20:30

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 AUG 2020 13:49

PC Open Date & Time

03 AUG 2020 13:31

PC Close Date & Time

03 AUG 2020 16:01

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:56:40

**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

03 AUG 2020 20:56

PC Open Date & Time

03 AUG 2020 16:56

PC Close Date & Time

04 AUG 2020 11:59

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:56:40

**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

04 AUG 2020 21:04

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:56:40

**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

05 AUG 2020 20:22

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:56:40

**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

06 AUG 2020 19:20

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:56:40

**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

07 AUG 2020 21:10

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:56:40

**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

08 AUG 2020 19:50

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:56:40

**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

09 AUG 2020 20:30

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:56:40

**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 ☐

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:56:40

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

No ☒

Yes ☐

PC Time stamp	03 AUG 2020 13:49
PC Open Date & Time	03 AUG 2020 13:31
PC Close Date & Time	03 AUG 2020 16:01

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:56:40

**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 ☐

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:56:40

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

No ☒

Yes ☐

PC Time stamp	03 AUG 2020 20:57
PC Open Date & Time	03 AUG 2020 16:56
PC Close Date & Time	04 AUG 2020 11:59

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:56:40

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 21:04
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:56:40

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:56:40

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 20:22
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:56:40

**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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Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:56:40

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 19:21
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:56:40

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 ☒

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:56:40

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 21:10
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:56:40

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

54 of 2406

EAB) (1725)

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:56:40

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 19:51
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

56 of 2406

EAB) (1725)

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:56:40

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 20:31
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3062048

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:17:48

Generated On: 09 Jun 2021 14:56:40

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3062048

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:17:48

Generated On: 09 Jun 2021 14:56:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062048

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:17:48

Generated On: 09 Jun 2021 14:56:40

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3062048

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:17:48

Generated On: 09 Jun 2021 14:56:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062048

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:17:48

Generated On: 09 Jun 2021 14:56:40

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3062048

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:17:48

Generated On: 09 Jun 2021 14:56:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062048

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 15:18:06

Generated On: 09 Jun 2021 14:56:40

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

Visit date (dd MMM yyyy)	31 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	VISIT2
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US3062048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 15:18:06

Generated On: 09 Jun 2021 14:56:40

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)	31 AUG 2020
Time of assessment (00:00-23:59)	11:25 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 11:25
Temperature (xxx.x)	96.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3062048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 15:18:06

Generated On: 09 Jun 2021 14:56:40

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)	31 AUG 2020
Time of assessment (00:00-23:59)	13:05 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 13:05
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3062048

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 15:18:06

Generated On: 09 Jun 2021 14:56:40

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

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

US3062048

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 15:18:06

Generated On: 09 Jun 2021 14:56:40

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) 31 AUG 2020

What was the treatment time? (00:00-23:59) 12:34 (24 HR)

Treatment Date and Time (derived) 31 AUG 2020 12:34

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

US3062048

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 15:18:06

Generated On: 09 Jun 2021 14:56:40

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

31 AUG 2020

Collection time (00:00-23:59)

11:30 (24 HR)

Collection date and time (derived)

31 AUG 2020 11:30

US3062048

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 15:18:06

Generated On: 09 Jun 2021 14:56:40

Collection date (dd MMM yyyy)			31 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:31	31 AUG 2020 11:31
Nasopharyngeal Swab 2	No		

US3062048

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:18:06

Generated On: 09 Jun 2021 14:56:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062048

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:56:40

**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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 13:10

PC Open Date & Time

31 AUG 2020 12:54

PC Close Date & Time

31 AUG 2020 15:24

US3062048

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:56:40

**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 97.4 °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	31 AUG 2020 19:51
PC Open Date & Time	31 AUG 2020 16:19
PC Close Date & Time	01 SEP 2020 11:59

US3062048

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:56:40

**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

98.6 °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 21:07

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3062048

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:56:40

**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

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 20:44

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3062048

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:56:40

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °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 23:22

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3062048

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 23:57

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3062048

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °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

05 SEP 2020 15:10

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3062048

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 12:04

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 13:11

PC Open Date & Time

31 AUG 2020 12:54

PC Close Date & Time

31 AUG 2020 15:24

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:56:40

**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

31 AUG 2020 19:52

PC Open Date & Time

31 AUG 2020 16:19

PC Close Date & Time

01 SEP 2020 11:59

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:56:40

**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

01 SEP 2020 21:08

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:56:40

**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

02 SEP 2020 20:45

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:56:40

**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

03 SEP 2020 23:22

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:56:40

**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

04 SEP 2020 23:55

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:56:40

**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

05 SEP 2020 15:10

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:56:40

**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

06 SEP 2020 12:04

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:56:40

**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 ☐

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:56:40

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 13:11
PC Open Date & Time	31 AUG 2020 12:54
PC Close Date & Time	31 AUG 2020 15:24

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:56:40

**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 ☐

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:56:40

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 19:53
PC Open Date & Time	31 AUG 2020 16:19
PC Close Date & Time	01 SEP 2020 11:59

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:56:40

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 21:09
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:56:40

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:56:40

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 20:45
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:56:40

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

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EAB) (1725)

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:56:40

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 23:23
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:56:40

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 23:56
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:56:40

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 ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:56:40

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 15:11
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:56:40

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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EAB) (1725)

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:56:40

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 12:04
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3062048

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:17:48

Generated On: 09 Jun 2021 14:56:40

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3062048

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:17:48

Generated On: 09 Jun 2021 14:56:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062048

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:17:48

Generated On: 09 Jun 2021 14:56:40

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3062048

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:17:48

Generated On: 09 Jun 2021 14:56:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062048

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 15:17:48

Generated On: 09 Jun 2021 14:56:40

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3062048

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:17:48

Generated On: 09 Jun 2021 14:56:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062048

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 15:18:06

Generated On: 09 Jun 2021 14:56:40

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	VISIT3

US3062048

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 15:18:06

Generated On: 09 Jun 2021 14:56:40

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 SEP 2020
Time of assessment (00:00-23:59)	08:03 (24 HR)
Vital Signs Date and Time (derived)	26 SEP 2020 08:03
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3062048

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 15:18:06

Generated On: 09 Jun 2021 14:56:40

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.*

US3062048

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 15:18:06

Generated On: 09 Jun 2021 14:56:40

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

Collection date (dd MMM yyyy)	26 SEP 2020
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Collection time (00:00-23:59)	08:14 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	26 SEP 2020 08:14
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US3062048

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 15:18:06

Generated On: 09 Jun 2021 14:56:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

<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	04 OCT 2020 17:27:16
Patient Cloud Open Date & Time	03 OCT 2020 00:01
Patient Cloud Close Date & Time	07 OCT 2020 23:59

US3062048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**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

11 OCT 2020 15:49:02

Patient Cloud Open Date & Time

10 OCT 2020 00:01

Patient Cloud Close Date & Time

14 OCT 2020 23:59

US3062048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 OCT 2020 06:10:19

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3062048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 NOV 2020 19:39:56

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3062048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 NOV 2020 10:08:47
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3062048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 NOV 2020 07:06:39

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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 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"/>

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Open Date & Time](#)

18 NOV 2020 00:01

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[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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 <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	27 NOV 2020 10:55:22
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 DEC 2020 05:46:17
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**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

09 DEC 2020 07:17:48

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**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

16 DEC 2020 07:31:26

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**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

25 DEC 2020 15:30:56

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**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

30 DEC 2020 07:08:09

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Open Date & Time](#)

06 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 JAN 2021 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	13 JAN 2021 06:13:29
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 JAN 2021 16:39:43

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 JAN 2021 21:24:10

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

<b>TIMEPOINT</b>	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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 FEB 2021 06:25:31
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

<b>TIMEPOINT</b>	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 FEB 2021 19:50:23
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**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

19 FEB 2021 09:52:48

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**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

24 FEB 2021 11:08:33

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**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

03 MAR 2021 09:15:54

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

<b>TIMEPOINT</b>	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 MAR 2021 18:38:27
Patient Cloud Open Date & Time	10 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**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

17 MAR 2021 06:37:55

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Open Date & Time](#)

24 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

28 MAR 2021 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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 <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"/>

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Open Date & Time](#)

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31 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 APR 2021 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**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

08 APR 2021 18:39:15

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 APR 2021 10:34:38

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 APR 2021 09:53:58

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 09:14:21

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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="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"/>

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Close Date & Time](#)

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09 MAY 2021 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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"/>

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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="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"/>

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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"/>

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Open Date & Time](#)

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26 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAY 2021 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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"/>

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**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°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 ☐

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 JUN 2021 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**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 ☐

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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"/>

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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"/>

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Open Date & Time](#)

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14 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 JUL 2021 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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 <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"/>

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**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 ☐

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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 <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"/>

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Open Date & Time](#)

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25 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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29 AUG 2021 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**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 ☐

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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"/>

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Close Date & Time](#)

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19 SEP 2021 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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 <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"/>

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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"/>

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 OCT 2021 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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"/>

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Close Date & Time](#)

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24 OCT 2021 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**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 ☐

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 OCT 2021 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Open Date & Time](#)

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03 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 NOV 2021 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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="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"/>

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Open Date & Time](#)

10 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**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 ☐

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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"/>

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Close Date & Time](#)

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28 NOV 2021 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	08 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 DEC 2021 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**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 ☐

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**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 ☐

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	22 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	26 DEC 2021 23:59
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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**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°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 ☐

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Close Date & Time](#)

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02 JAN 2022 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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 <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"/>

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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"/>

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**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 ☐

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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 <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"/>

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Close Date & Time](#)

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30 JAN 2022 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**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 ☐

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**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 ☐

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Close Date & Time](#)

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13 FEB 2022 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**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 ☐

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Close Date & Time](#)

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20 FEB 2022 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**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 ☐

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Close Date & Time](#)

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27 FEB 2022 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

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

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

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Close Date & Time](#)

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06 MAR 2022 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**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 ☐

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 MAR 2022 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**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 ☐

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Close Date & Time](#)

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20 MAR 2022 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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"/>

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Close Date & Time](#)

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27 MAR 2022 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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"/>

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Close Date & Time](#)

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03 APR 2022 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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"/>

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Close Date & Time](#)

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17 APR 2022 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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"/>

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Close Date & Time](#)

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24 APR 2022 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

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

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

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Close Date & Time](#)

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01 MAY 2022 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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"/>

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Close Date & Time](#)

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22 MAY 2022 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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 <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"/>

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Open Date & Time](#)

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25 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 MAY 2022 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**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 ☐ Yes ☐

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

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Close Date & Time](#)

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05 JUN 2022 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**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 ☐

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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="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"/>

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Close Date & Time](#)

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19 JUN 2022 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**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 ☐  
Yes ☐

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

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Close Date & Time](#)

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10 JUL 2022 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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 <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"/>

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Close Date & Time](#)

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24 JUL 2022 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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"/>

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Close Date & Time](#)

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07 AUG 2022 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this 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>	10 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	14 AUG 2022 23:59
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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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"/>

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Close Date & Time](#)

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21 AUG 2022 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**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 ☐

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this 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 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	28 AUG 2022 23:59
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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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"/>

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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"/>

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

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

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

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

**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 ☐

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

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US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

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 <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"/>

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3062048

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3062048**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	05 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	09 OCT 2022 23:59
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**US3062048**

**Folder: Cosmetic Injections and Dermal Fillers**

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

**Generated On: 09 Jun 2021 14:56:40**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 11:58:05

US3062048

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 15 Mar 2021 22:08:47

Generated On: 09 Jun 2021 14:56:40

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3062048

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 15 Mar 2021 22:08:47

Generated On: 09 Jun 2021 14:56:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062048

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:20:53

Generated On: 09 Jun 2021 14:56:40

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3062048

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:20:53

Generated On: 09 Jun 2021 14:56:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062048

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:20:53

Generated On: 09 Jun 2021 14:56:40

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 DEC 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3062048

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:20:53

Generated On: 09 Jun 2021 14:56:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062048

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:20:53

Generated On: 09 Jun 2021 14:56:40

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

*If Contact Not Made, please provide Comments*

US3062048

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:20:53

Generated On: 09 Jun 2021 14:56:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062048

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:20:53

Generated On: 09 Jun 2021 14:56:40

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

Visit date (dd MMM yyyy)	22 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	VISIT4
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US3062048

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 20:20:53

Generated On: 09 Jun 2021 14:56:40

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 FEB 2021
Time of assessment (00:00-23:59)	08:05 (24 HR)
Vital Signs Date and Time (derived)	22 FEB 2021 08:05
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3062048

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 20:20:53

Generated On: 09 Jun 2021 14:56:40

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.*

US3062048

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:20:53

Generated On: 09 Jun 2021 14:56:40

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 FEB 2021

Collection time (00:00-23:59)

08:22 (24 HR)

Collection date and time (derived)

22 FEB 2021 08:22

US3062048

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:20:53

Generated On: 09 Jun 2021 14:56:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3062048

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 20:20:53

Generated On: 09 Jun 2021 14:56:40

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3062048

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 20:20:53

Generated On: 09 Jun 2021 14:56:40

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3062048**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

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*

**US3062048**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:40**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3062048**

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

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 14:56:40**

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"/>

**US3062048**

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

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

**Generated On: 09 Jun 2021 14:56:40**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3062048

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 20:20:53

Generated On: 09 Jun 2021 14:56:40

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

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

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

Folder OID	UNBLND_DECIDE
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US3062048

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 20:20:53

Generated On: 09 Jun 2021 14:56:40

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

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 26 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

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

US3062048

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 20:20:53

Generated On: 09 Jun 2021 14:56:40

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)	14:09 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	26 JAN 2021 14:09
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US3062048

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 20:20:53

Generated On: 09 Jun 2021 14:56:40

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)	14:06
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Collection Date and Time (derived)	26 JAN 2021 14:06
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US3062048

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 31 Mar 2021 20:53:53

Generated On: 09 Jun 2021 14:56:40

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

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US3062048

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 31 Mar 2021 20:53:52

Generated On: 09 Jun 2021 14:56:40

AEID USA-US090-2021-MRNA-1273-P30  
1000002

Adverse event LUMBAR RADICULOPATHY  
INVOLVING THE LEFT S1  
NERVE ROOT

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) 11 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes ☐  
No ☒

If not Ongoing, end date (dd MMM yyyy) 12 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild ☐  
Grade 2/Moderate ☐  
Grade 3/Severe ☐  
Grade 4 ☒

Is the adverse event serious? Yes ☒  
No ☐

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 11 JAN 2021

Hospital Discharge Date (dd MMM yyyy) 12 JAN 2021

Admitted to ICU? Yes ☐  
No ☒

PRODUCTION RELEASE (v12.003 324 of 2406  
EAB) (1725)

US3062048

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 31 Mar 2021 20:53:52

Generated On: 09 Jun 2021 14:56:40

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

US3062048

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 31 Mar 2021 20:53:52

Generated On: 09 Jun 2021 14:56:40

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AT SCREENING VISIT, SUBJECT REPORTED LOW BACK PAIN BEGINNING IN 1964. ON 1/14/21, SUBJECT REPORTED THAT HIS LOW BACK PAIN BEGAN WORSENING PRIOR TO STUDY START AND WAS RECEIVING CONSERVATIVE TREATMENT, EPIDURAL INJECTION AND PHYSICAL THERAPY. CONSERVATIVE TREATMENT WAS INEFFECTIVE, THEREFORE, SUBJECT WAS SCHEDULED FOR LAMINECTOMY. SUBJECT REPORTS LAMINECTOMY ON 11JAN2021 WITH NO ISSUES OR CONCERNS. SUBJECT REPORTS HE WAS GIVEN MEDICATION WHILE IN THE HOSPITAL, BUT UNCERTAIN OF NAMES AND DOSAGES. SUBJECT WAS THEN RELEASED FROM HOSPITAL ON 12JAN2021. RELEASE OF RECORDS MAILED TO SUBJECT. UPDATE TO BE PROVIDED UPON RECEIPT OF NEW INFORMATION. RECEIVED MEDICAL RECORDS 1/19/2021. CHANGED SAE TERM FROM LOW BACK PAIN TO LUMBAR RADICULOPATHY INVOLVING THE LEFT S1 NERVE ROOT. PRIOR TO SURGERY PRE OP MRI AND X-RAY PERFORMED.

US3062048

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 31 Mar 2021 20:53:52

Generated On: 09 Jun 2021 14:56:40

MRI AND X-RAY SHOW  
LUMBAR LATERAL RECESS  
STENOSIS AT L5-S1 ON THE  
LEFT SIDE AND LEFT L5-S1  
LUMBAR FACET SYNOVIAL  
CYST. SURGERY PERFORMED  
WAS A LEFT HEMI  
LAMINOTOMY  
DECOMPRESSION WITH  
PARTIAL MEDIAL  
FACETECTOMY AND EXCISION  
OF L5-S1 FACET SYNOVIAL  
CYST. SOURCE UPDATED WITH  
MEDICATION, PROCEDURES,  
AND AES

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

US3062048

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 31 Mar 2021 20:53:52

Generated On: 09 Jun 2021 14:56:40

AEID

Adverse event

INCIDENTAL DUROTOMY

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)

11 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

12 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 31 Mar 2021 20:53:52

Generated On: 09 Jun 2021 14:56:40

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

US3062048

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 31 Mar 2021 20:53:52

Generated On: 09 Jun 2021 14:56:40

AEID	
Adverse event	LIGAMENTUM FLAVUM HYPERTROPHY
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)	11 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 31 Mar 2021 20:53:52

Generated On: 09 Jun 2021 14:56:40

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 31 Mar 2021 20:53:52

Generated On: 09 Jun 2021 14:56:40

AEID	
Adverse event	LUMBAR DISC DEGENERATION
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)	11 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 31 Mar 2021 20:53:52

Generated On: 09 Jun 2021 14:56:40

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

US3062048

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 31 Mar 2021 20:53:52

Generated On: 09 Jun 2021 14:56:40

AEID

Adverse event

LEFT L5-S1 LUMBAR FACET  
SYNOVIAL CYST

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)

11 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

12 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 31 Mar 2021 20:53:52

Generated On: 09 Jun 2021 14:56:40

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 31 Mar 2021 20:53:52

Generated On: 09 Jun 2021 14:56:40

AEID

Adverse event

LUMBAR LATERAL RECESS  
STENOSIS AT L5-S1 ON THE  
LEFT SIDE

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)

11 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

12 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 31 Mar 2021 20:53:52

Generated On: 09 Jun 2021 14:56:40

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

US3062048

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 31 Mar 2021 20:53:52

Generated On: 09 Jun 2021 14:56:40

AEID

Adverse event

HEADACHE

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)

11 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

12 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 31 Mar 2021 20:53:52

Generated On: 09 Jun 2021 14:56:40

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

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 20:20:53

Generated On: 09 Jun 2021 14:56:40

---

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

Yes ☒

No ☐

---

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

---

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

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 (1)

Data signed: (b) (4) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

	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)	02 MAY 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

Name of Medication AMLODIPINE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

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 (2)

Data signed: (b) (4) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

Name of Medication BENAZEPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

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 (3)

Data signed: (b) (4) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	29 APR 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

Name of Medication SPIRONOLACTONE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

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 (4)

Data signed: (b) (4) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

	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 JUL 2018	
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) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

Name of Medication GLUCOSAMINE CHONDROITIN

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 150

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) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

	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 (6)

Data signed: (b) (4) 09 Apr 2021 13:19:50

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Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒  
No ☐

Indication NUTRITIONAL SUPPLEMENT

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 (6)

Data signed: (b) (4) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

	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) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication SCIATICA, LEFT

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

	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 2001	
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 (8)

Data signed: (b) (4) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

Name of Medication DICLOFENAC SODIUM

Prophylaxis Yes ☐  
No ☒

Indication LOW BACK PAIN

Dose per administration 75

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) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

	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)		05 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

Name of Medication CYCLOBENZAPINE

Prophylaxis Yes ☐  
No ☒

Indication LOW BACK PAIN

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

	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)		05 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		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 (10)

Data signed: (b) (4) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

Name of Medication ECOTRIN

Prophylaxis Yes ☐  
No ☒

Indication LUMBAR RADICULOPATHY  
INVOLVING THE LEFT S1  
NERVE ROOT

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	12 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

Name of Medication ULTRAM(TRAMADOL)

Prophylaxis Yes ☐  
No ☒

Indication LUMBAR RADICULOPATHY  
INVOLVING THE LEFT S1  
NERVE ROOT

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	12 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication LUMBAR RADICULOPATHY  
INVOLVING THE LEFT S1  
NERVE ROOT

Dose per administration 650

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 (12)

Data signed: (b) (4) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

	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)	11 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

Name of Medication NORMAL SALINE

Prophylaxis Yes ☐  
No ☒

Indication LUMBAR RADICULOPATHY  
INVOLVING THE LEFT S1  
NERVE ROOT

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 200 ML/HOUR

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) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

	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)	11 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

Name of Medication NOZIN NASAL SWAB

Prophylaxis Yes ☐  
No ☒

Indication LUMBAR RADICULOPATHY  
INVOLVING THE LEFT S1  
NERVE ROOT

Dose per administration 2

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

If dose unit is Other, specify SWAB

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) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input checked="" 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)	11 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		11 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐  
No ☒

Indication LUMBAR RADICULOPATHY  
INVOLVING THE LEFT S1  
NERVE ROOT

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 (15)

Data signed: (b) (4) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

	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)	11 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

Name of Medication THROMBIN

Prophylaxis Yes ☐  
No ☒

Indication LUMBAR RADICULOPATHY  
INVOLVING THE LEFT S1  
NERVE ROOT

Dose per administration 10000

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

If dose unit is Other, specify UNITS

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) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

	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)	11 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

Name of Medication MARCAINE 0.5%

Prophylaxis Yes ☐  
No ☒

Indication LUMBAR RADICULOPATHY  
INVOLVING THE LEFT S1  
NERVE ROOT

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

	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)	11 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

Name of Medication LACTATED RINGERS

Prophylaxis Yes ☐  
No ☒

Indication LUMBAR RADICULOPATHY  
INVOLVING THE LEFT S1  
NERVE ROOT

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 50 ML/HOUR

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) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

	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)	11 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

Name of Medication KEFZOL

Prophylaxis Yes ☐  
No ☒

Indication LUMBAR RADICULOPATHY  
INVOLVING THE LEFT S1  
NERVE ROOT

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

	Intraocular	<input 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 checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	11 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		11 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 09 Apr 2021 13:19:50

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Name of Medication DEPO-MEDROL

Prophylaxis Yes ☐  
No ☒

Indication LOW BACK PAIN

Dose per administration 80

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) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify		EPIDURAL
Start date (dd MMM yyyy)		05 NOV 2020
Start date completely unknown		False
Ongoing?		Yes <input type="radio"/>
		No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		05 NOV 2020
Was this medication taken for solicited event?		Yes <input type="radio"/>
		No <input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)		802 <input type="radio"/>
		803 <input type="radio"/>
		804 <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

Name of Medication SURGIFLO

Prophylaxis Yes ☐  
No ☒

Indication LUMBAR RADICULOPATHY  
INVOLVING THE LEFT S1  
NERVE ROOT

Dose per administration 8

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

	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)	11 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

Name of Medication POLYETHYLENE GLYCOL  
ESTER AND TRILYSINE AMINE  
SOLUTION

Prophylaxis Yes ☐  
No ☒

Indication INCIDENTAL DUROTOMY

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☒  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

	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)	11 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

Name of Medication METHYLPREDNISONE

Prophylaxis Yes ☐  
No ☒

Indication LOW BACK PAIN

Dose per administration 80

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) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	EPIDURAL	
Start date (dd MMM yyyy)	1 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	1 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

Name of Medication B12 VITAMIN

Prophylaxis Yes ☒  
No ☐

Indication LOW BACK PAIN

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 09 Apr 2021 13:19:50

Generated On: 09 Jun 2021 14:56:40

	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)	27 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 20:20:53

Generated On: 09 Jun 2021 14:56:40

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3062048

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 02 Apr 2021 20:20:53

Generated On: 09 Jun 2021 14:56:40

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
11 JAN 2021	EXCISION OF L5-S1 FACET SYNOVIAL CYST	Adverse Event	
11 JAN 2021	LEFT L5-S1 HEMILAMINOTOMY DECOMPRESSION WITH PARTIAL FACETECTOMY	Adverse Event	
11 JAN 2021	MRI	Adverse Event	
11 JAN 2021	X-RAY	Adverse Event	
11 NOV 2020	LUMBAR EPIDURAL	Medical History	

US3062048

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:56:40

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

US3062048

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:56:40

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 ☐

US3062048

Folder: SAE USA-US090-2021-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 02 Apr 2021 20:20:53

Generated On: 09 Jun 2021 14:56:40

SAEID	USA-US090-2021-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3062048

Folder: SAE USA-US090-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 02 Apr 2021 20:20:53

Generated On: 09 Jun 2021 14:56:40

SAEID	USA-US090-2021-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	15/JAN/2021 13:35
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3062048

Folder: SAE USA-US090-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 02 Apr 2021 20:20:53

Generated On: 09 Jun 2021 14:56:40

SAEID	USA-US090-2021-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	21/JAN/2021 12:08
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3062048

Folder: SAE USA-US090-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 02 Apr 2021 20:20:53

Generated On: 09 Jun 2021 14:56:40

SAEID	USA-US090-2021-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	GLOVER
Site Address: Street	700 MEDICAL CENTER DR.
Site Address: City	NEWTON
Site Address: State	KS
Site Address: Postal Code	67114
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	16/FEB/2021 10:56
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3062048 (Prod: Alliance for Multispecialty Research, LLC)

**US3062048**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 14:56:40**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
User entered 'US3062048'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 16:49:10

**US3062048**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:40**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	03 Aug 2020 18:17:34
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
User entered '03 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 16:49:11

**US3062048**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'Clinic (Clinic)'	Sherry Henning (b) (4)	03 Aug 2020 18:17:34
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:40**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User entered 'SCRN'	System	03 Aug 2020 18:17:34

**US3062048**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:56:40**

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
User entered (b) (6) 1949'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 16:49:12

**US3062048**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:56:40**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
User entered '70'	(b) (4) Sherry Henning (b) (4) (b) (4)	03 Aug 2020 18:17:47

**US3062048**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:56:40**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User entered 'YEARS'	System	03 Aug 2020 18:17:47

**US3062048**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:56:40**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User entered '70'	System	03 Aug 2020 18:18:03

**US3062048**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:56:40**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered 'Male (M)'	Sherry Henning (b) (4)	03 Aug 2020 18:17:47
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:56:40**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Sherry Henning (b) (4)	03 Aug 2020 18:17:47
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:56:40**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered 'I'	Sherry Henning (b) (4)	03 Aug 2020 18:17:47
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:56:40**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	03 Aug 2020 18:17:47
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:56:40**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	03 Aug 2020 18:17:47
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:56:40**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	03 Aug 2020 18:17:47
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:56:40**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
User entered '0'	Sherry Henning (b) (4)	03 Aug 2020 18:17:47

**US3062048**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:56:40**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	03 Aug 2020 18:17:47
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:56:40**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	03 Aug 2020 18:17:47
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:56:40**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	03 Aug 2020 18:17:47
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 14:56:40**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	03 Aug 2020 18:17:47
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:56:40**

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered '3 Aug 2020'	Sherry Henning (b) (4)	03 Aug 2020 18:18:03
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User entered 'Aug 2020'	System	03 Aug 2020 18:18:03

**US3062048**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User entered '2020'	System	03 Aug 2020 18:18:03

**US3062048**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:56:40**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered 'Amendment 1 (1)'	Sherry Henning (b) (4)	03 Aug 2020 18:18:03
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	03 Aug 2020 18:18:03
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:56:40**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
User entered empty.	(b) (4) Sherry Henning (b) (4) (b) (4)	03 Aug 2020 18:18:03

**US3062048**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:56:40**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
User entered empty.	(b) (4) Sherry Henning (b) (4) (b) (4)	03 Aug 2020 18:18:03

**US3062048**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:56:40**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered 'No (N)'	Sherry Henning (b) (4)	03 Aug 2020 18:18:03
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:56:40**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 16:49:11

**US3062048**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 14:56:40**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User entered 'I'	System	03 Aug 2020 18:18:10

**US3062048**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	03 Aug 2020 18:18:10
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 09 Jun 2021 14:56:40**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	04 Aug 2020 21:22:12
	(b) (4)	

US3062048

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:56:40

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	04 Aug 2020 21:30:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 21:30:11
Data point term sent to Coder	System	04 Aug 2020 21:28:53
User entered 'hypertension'	Sherry Henning (b) (4) (b) (4)	04 Aug 2020 21:28:42

**US3062048**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
User entered 'un UNK 2014'	(b) (4) Sherry Henning (b) (4)	04 Aug 2020 21:28:42

**US3062048**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	04 Aug 2020 21:28:42
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	04 Aug 2020 21:28:42
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
User entered empty.	(b) (4) Sherry Henning (b) (4)	04 Aug 2020 21:28:42

**US3062048**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	04 Aug 2020 21:28:42
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User entered 'Jan 2014'	System	04 Aug 2020 21:28:42

**US3062048**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User entered '2014'	System	04 Aug 2020 21:28:42

**US3062048**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User entered empty.	System	04 Aug 2020 21:28:42

**US3062048**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User entered empty.	System	04 Aug 2020 21:28:42

US3062048

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:56:40

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	04 Aug 2020 21:31:04
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Aug 2020 21:31:04
	(b) (4)	
Data point term sent to Coder	System	04 Aug 2020 21:29:53
User entered 'hyperlipidemia'	Sherry Henning (b) (4)	04 Aug 2020 21:29:06
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered '28 Apr 2016'	Sherry Henning (b) (4)	04 Aug 2020 21:29:06
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	04 Aug 2020 21:29:06
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:56:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
User entered 'Yes (Y)'	(b) (4) Sherry Henning (b) (4) (b) (4)	04 Aug 2020 21:29:06

**US3062048**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
User entered empty.	(b) (4) Sherry Henning (b) (4)	04 Aug 2020 21:29:06

**US3062048**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:56:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	04 Aug 2020 21:29:06
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User entered 'Apr 2016'	System	04 Aug 2020 21:29:06

**US3062048**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User entered '2016'	System	04 Aug 2020 21:29:06

**US3062048**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User entered empty.	System	04 Aug 2020 21:29:06

**US3062048**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User entered empty.	System	04 Aug 2020 21:29:06

US3062048

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:56:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Lumbar spinal cord and nerve root disorders, PT: Sciatica, LLT: Sciatica - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	12 Aug 2020 14:35:11
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 14:35:11
Data point term sent to Coder	System	04 Aug 2020 21:31:57
User entered 'Sciatia, left'	Sherry Henning (b) (4) (b) (4)	04 Aug 2020 21:31:46

**US3062048**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
User entered 'un UNK 1964'	(b) (4) Sherry Henning (b) (4) (b) (4)	04 Aug 2020 21:31:46

**US3062048**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	04 Aug 2020 21:31:46
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:56:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	04 Aug 2020 21:31:46
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
User entered empty.	Sherry Henning (b) (4)	04 Aug 2020 21:31:46

**US3062048**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:56:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	04 Aug 2020 21:31:46
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User entered 'Jan 1964'	System	04 Aug 2020 21:31:46

**US3062048**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User entered '1964'	System	04 Aug 2020 21:31:46

**US3062048**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User entered empty.	System	04 Aug 2020 21:31:46

**US3062048**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User entered empty.	System	04 Aug 2020 21:31:46

US3062048

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:56:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\\23.0.	Coder Import (b) (4)	12 Feb 2021 17:46:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Feb 2021 17:46:49
Data point term sent to Coder	System	12 Feb 2021 17:45:44
User entered 'low back pain'	marissa Mueller (b) (4)	12 Feb 2021 17:44:52
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
User entered 'un UNK 1964'	(b) (4) marissa Mueller (b) (4)	12 Feb 2021 17:44:52
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
User entered '0'	(b) (4) marissa Mueller (b) (4)	12 Feb 2021 17:44:52
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:56:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered 'Yes (Y)'	marissa Mueller (b) (4)	12 Feb 2021 17:44:52
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
User entered empty.	(b) (4) marissa Mueller (b) (4)	12 Feb 2021 17:44:52
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:56:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
User entered '0'	(b) (4) marissa Mueller (b) (4)	12 Feb 2021 17:44:52
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User entered 'Jan 1964'	System	12 Feb 2021 17:44:52

**US3062048**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User entered '1964'	System	12 Feb 2021 17:44:52

**US3062048**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User entered empty.	System	12 Feb 2021 17:44:52

**US3062048**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User entered empty.	System	12 Feb 2021 17:44:52

US3062048

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:56:40

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Physiotherapy, LLT: Physical therapy - version MedDRA\\23.0.	Coder Import (b) (4)	16 Mar 2021 19:10:53
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Mar 2021 19:10:53
	(b) (4)	
Data point term sent to Coder	System	16 Mar 2021 19:09:32
User entered 'physical therapy'	Riley King (b) (4)	16 Mar 2021 19:08:34
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
User entered '12 Jun 2020'	Riley King (b) (4)	16 Mar 2021 19:08:34
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
User entered '0'	(b) (4) Riley King (b) (4) (b) (4)	16 Mar 2021 19:08:34

**US3062048**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:56:40**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	16 Mar 2021 19:08:34
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
User entered '20 Jun 2020'	Riley King (b) (4)	16 Mar 2021 19:08:34
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:56:40**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
User entered '0'	(b) (4) Riley King (b) (4) (b) (4)	16 Mar 2021 19:08:34

**US3062048**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User entered 'Jun 2020'	System	16 Mar 2021 19:08:34

**US3062048**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User entered '2020'	System	16 Mar 2021 19:08:34

**US3062048**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User entered 'Jun 2020'	System	16 Mar 2021 19:08:34

**US3062048**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User entered '2020'	System	16 Mar 2021 19:08:34

**US3062048**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
User entered 'Yes (Y)'	Sherry Henning (b) (4)	04 Aug 2020 21:33:38

**US3062048**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '03 Aug 2020'	Sherry Henning (b) (4)	04 Aug 2020 21:33:38
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '11:36'	Sherry Henning (b) (4)	04 Aug 2020 21:33:38
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User entered '03 Aug 2020 11:36'	System	04 Aug 2020 21:33:38

**US3062048**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '177.0' cm	Sherry Henning (b) (4)	04 Aug 2020 21:33:38
	(b) (4)	
DataPoint set to visible.	System	03 Aug 2020 18:18:10

**US3062048**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
User entered '96.8' kg	Sherry Henning (b) (4)	04 Aug 2020 21:33:38
DataPoint set to visible.	System	03 Aug 2020 18:18:10

**US3062048**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
Amendment Manager: User entered '30.89789'	System	16 Sep 2020 23:41:19
User entered '30.9'	System	04 Aug 2020 21:33:38
DataPoint set to visible.	System	03 Aug 2020 18:18:10

**US3062048**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User entered 'kg/m2'	System	04 Aug 2020 21:33:38
DataPoint set to visible.	System	03 Aug 2020 18:18:10

US3062048

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 21:07:27
	(b) (4)	
User entered '96.6' F	Sherry Henning (b) (4)	04 Aug 2020 21:33:38
	(b) (4)	

US3062048

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered empty; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 21:07:27
	(b) (4)	
User entered 'Oral (Oral)'	Sherry Henning (b) (4)	04 Aug 2020 21:33:38
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	04 Aug 2020 21:33:38
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 21:07:27
User entered '60'	(b) (4)	
	Sherry Henning (b) (4)	04 Aug 2020 21:33:38
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User entered 'bpm'	System	04 Aug 2020 21:33:38

US3062048

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 21:07:27
User entered '16'	(b) (4)	
	Sherry Henning (b) (4)	04 Aug 2020 21:33:38
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User entered 'breaths/min'	System	04 Aug 2020 21:33:38

US3062048

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 21:07:27
User entered '130'	Sherry Henning (b) (4)	04 Aug 2020 21:33:38
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User entered 'mmHg'	System	04 Aug 2020 21:33:38

US3062048

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 21:07:27
	(b) (4)	
User entered '80'	Sherry Henning (b) (4)	04 Aug 2020 21:33:38
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User entered 'mmHg'	System	04 Aug 2020 21:33:38

**US3062048**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05

**US3062048**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05

US3062048

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 21:08:00
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Sherry Henning (b) (4)	04 Aug 2020 22:39:24
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	04 Aug 2020 21:38:03
	(b) (4)	

US3062048

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4)	06 Sep 2020 13:12:11
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		31 Aug 2020 17:37:25
User entered '03 Aug 2020' reason for change: Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 21:08:00
User entered empty; reason for change Data Entry Error	Sherry Henning (b) (4)	04 Aug 2020 22:39:24
User entered '3 Aug 2020'	Sherry Henning (b) (4)	04 Aug 2020 21:38:03

**US3062048**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'No (N)'	Sherry Henning (b) (4)	04 Aug 2020 21:39:53
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'No (N)'	Sherry Henning (b) (4)	04 Aug 2020 21:39:53
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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**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)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'No (N)'	Sherry Henning (b) (4)	04 Aug 2020 21:39:53
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:40

**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)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	04 Aug 2020 21:39:53
	(b) (4)	

US3062048

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:40

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'No (N)'	Sherry Henning (b) (4)	04 Aug 2020 21:39:53
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[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)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'No (N)'	Sherry Henning (b) (4)	04 Aug 2020 21:39:53
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:40

**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)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
User entered 'No (N)'	Sherry Henning (b) (4)	04 Aug 2020 21:39:53

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Folder: Screening

Form: Risk of Exposure

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**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)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
User entered 'No (N)'	(b) (4) Sherry Henning (b) (4)	04 Aug 2020 21:39:53

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Folder: Screening

Form: Risk of Exposure

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[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)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'No (N)'	Sherry Henning (b) (4)	04 Aug 2020 21:39:53
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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**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)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'No (N)'	Sherry Henning (b) (4)	04 Aug 2020 21:39:53
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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**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)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
User entered 'No (N)'	Sherry Henning (b) (4)	04 Aug 2020 21:39:53

**US3062048**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 14:56:40**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'No (N)'	Sherry Henning (b) (4)	04 Aug 2020 21:39:53
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 14:56:40**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	04 Aug 2020 21:39:53
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 14:56:40**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'I'	Sherry Henning (b) (4)	04 Aug 2020 21:39:53
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:40

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	04 Aug 2020 21:39:53
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:40

**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)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
User entered '0'	Sherry Henning (b) (4)	04 Aug 2020 21:39:53

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:40

[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)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	04 Aug 2020 21:39:53
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:40

**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)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
User entered '0'	Sherry Henning (b) (4)	04 Aug 2020 21:39:53

**US3062048**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 14:56:40**

**Resides in a single family home** (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	04 Aug 2020 21:39:53
	(b) (4)	

**US3062048**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 14:56:40**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	04 Aug 2020 21:39:53
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:56:40

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:12:05
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	04 Aug 2020 21:39:53
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:40**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	03 Aug 2020 18:18:30
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '3 Aug 2020'	Sherry Henning (b) (4)	03 Aug 2020 18:18:30
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'Clinic (Clinic)'	Sherry Henning (b) (4)	03 Aug 2020 18:18:30
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:40**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered 'VISIT1'	System	03 Aug 2020 18:18:30

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '03 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 17:54:10

US3062048

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:56:40

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:45:50
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:45:50
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	03 Aug 2020 17:54:10
User entered '184428' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 17:54:10

US3062048

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:56:40

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 17:54:10

US3062048

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:56:40

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'No (N)'	Sherry Henning (b) (4)	03 Aug 2020 18:20:16
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 14:56:40**

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'No (N)'	Sherry Henning (b) (4)	03 Aug 2020 18:20:16
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 14:56:40**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'No (N)'	Sherry Henning (b) (4)	03 Aug 2020 18:20:16
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 14:56:40**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'No (N)'	Sherry Henning (b) (4)	03 Aug 2020 18:20:16
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 14:56:40**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'No (N)'	Sherry Henning (b) (4)	03 Aug 2020 18:20:16
	(b) (4)	

US3062048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:56:40

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 21:07:46
	(b) (4)	
User entered '177.0' cm	Sherry Henning (b) (4)	04 Aug 2020 21:36:06
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:56:40

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 21:07:46
	(b) (4)	
User entered '96.8' kg	Sherry Henning (b) (4)	04 Aug 2020 21:36:06
	(b) (4)	

US3062048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:56:40

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 21:07:46
	(b) (4)	
User entered '177.0' cm	Sherry Henning (b) (4)	04 Aug 2020 21:36:06
	(b) (4)	

US3062048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:56:40

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 21:07:46
User entered '96.8' kg	Sherry Henning (b) (4)	04 Aug 2020 21:36:06
	(b) (4)	

US3062048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User accepted default value 'Pre-Dose (PREDOSE)'	Sherry Henning (b) (4) (b) (4)	04 Aug 2020 21:36:06

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	04 Aug 2020 21:36:06
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '3 Aug 2020'	Sherry Henning (b) (4)	04 Aug 2020 21:36:06
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '11:36'	Sherry Henning (b) (4)	04 Aug 2020 21:36:06
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered '3 Aug 2020 11:36'	System	04 Aug 2020 21:36:06

US3062048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
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) (6)	24 Sep 2020 06:51:30
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.'	Colton King (b) (4)	23 Sep 2020 16:09:52
answered with 'NCS per PI' (Site from System).	(b) (4)	
Amendment Manager: 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	16 Sep 2020 23:41:19
User entered '96.6' F	Sherry Henning (b) (4)	04 Aug 2020 21:36:06
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'Oral (Oral)'	Sherry Henning (b) (4)	04 Aug 2020 21:36:06
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:40**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	04 Aug 2020 21:36:06
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '60'	Sherry Henning (b) (4)	04 Aug 2020 21:36:06
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered 'bpm'	System	04 Aug 2020 21:36:06

US3062048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '16'	Sherry Henning (b) (4)	04 Aug 2020 21:36:06
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered 'breaths/min'	System	04 Aug 2020 21:36:06

US3062048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '130'	Sherry Henning (b) (4)	04 Aug 2020 21:36:06
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered 'mmHg'	System	04 Aug 2020 21:36:06

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '80'	Sherry Henning (b) (4)	04 Aug 2020 21:36:06
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered 'mmHg'	System	04 Aug 2020 21:36:06

US3062048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:56:40

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 21:07:46
	(b) (4)	
User entered '177.0' cm	Sherry Henning (b) (4)	04 Aug 2020 21:36:06
	(b) (4)	

US3062048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:56:40

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 21:07:46
	(b) (4)	
User entered '96.8' kg	Sherry Henning (b) (4)	04 Aug 2020 21:36:06
	(b) (4)	

US3062048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User accepted default value 'Post-Dose (POSTDOSE)'	Sherry Henning (b) (4) (b) (4)	04 Aug 2020 21:36:06

US3062048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	04 Aug 2020 21:36:06
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:56:40**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '3 Aug 2020'	Sherry Henning (b) (4)	04 Aug 2020 21:36:06
	(b) (4)	

US3062048

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	10 Aug 2020 11:14:47
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'correct as entered' (Site from System).	Sherry Henning (b) (4)	04 Aug 2020 21:37:35
	(b) (4)	
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		04 Aug 2020 21:36:06
User entered '13:43'	Sherry Henning (b) (4)	04 Aug 2020 21:36:06
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered '3 Aug 2020 13:43'	System	04 Aug 2020 21:36:06

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
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) (6)	24 Sep 2020 06:51:34
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.'	Colton King (b) (4)	23 Sep 2020 16:10:03
answered with 'NCS per PI' (Site from System).	(b) (4)	
Amendment Manager: 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	16 Sep 2020 23:41:19
User entered '96.1' F	Sherry Henning (b) (4)	04 Aug 2020 21:36:06
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:56:40**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'Oral (Oral)'	Sherry Henning (b) (4)	04 Aug 2020 21:36:06
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:56:40**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	04 Aug 2020 21:36:06
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:56:40**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '58'	Sherry Henning (b) (4)	04 Aug 2020 21:36:06
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:56:40**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered 'bpm'	System	04 Aug 2020 21:36:06

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '16'	Sherry Henning (b) (4)	04 Aug 2020 21:36:06
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:56:40**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered 'breaths/min'	System	04 Aug 2020 21:36:06

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '136'	Sherry Henning (b) (4)	04 Aug 2020 21:36:06
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:56:40**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered 'mmHg'	System	04 Aug 2020 21:36:06

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '86'	Sherry Henning (b) (4)	04 Aug 2020 21:36:06
	(b) (4)	

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:56:40**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered 'mmHg'	System	04 Aug 2020 21:36:06

US3062048

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 21:08:08
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	04 Aug 2020 21:37:51
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:56:40**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered empty; reason for change Data Entry Error	Brianna Burton (b) (4)	26 Aug 2020 21:08:08
	(b) (4)	
User entered '3 Aug 2020'	Sherry Henning (b) (4)	04 Aug 2020 21:37:51
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:56:40**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	03 Aug 2020 18:20:39
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:56:40**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	03 Aug 2020 18:20:39
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:56:40

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 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
User entered empty.	(b) (4) Sherry Henning (b) (4)	03 Aug 2020 18:20:39

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:56:40**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered 'MRNA-1273 OR PLACEBO'	System	03 Aug 2020 18:20:39

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:56:40

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '3 Aug 2020'	Sherry Henning (b) (4)	03 Aug 2020 18:20:39
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:56:40**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '13:11'	Sherry Henning (b) (4)	03 Aug 2020 18:20:39
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:56:40**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered '3 Aug 2020 13:11'	System	03 Aug 2020 18:20:39

US3062048

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:56:40

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Sherry Henning (b) (4)	03 Aug 2020 18:20:39
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:56:40

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered 'ONCE'	System	03 Aug 2020 18:20:39

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:56:40**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered 'INTRAMUSCULAR'	System	03 Aug 2020 18:20:39

US3062048

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	04 Aug 2020 21:40:53
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:56:40**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '3 Aug 2020'	Sherry Henning (b) (4)	04 Aug 2020 21:40:53
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:56:40**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '12:21'	Sherry Henning (b) (4)	04 Aug 2020 21:40:53
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:56:40**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered '3 Aug 2020 12:21'	System	04 Aug 2020 21:40:53

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 09 Jun 2021 14:56:40**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '3 Aug 2020'	Sherry Henning (b) (4)	04 Aug 2020 21:41:40
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Sherry Henning (b) (4) (b) (4)	04 Aug 2020 21:41:40

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	04 Aug 2020 21:41:40
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '12:24'	Sherry Henning (b) (4)	04 Aug 2020 21:41:40
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered '3 Aug 2020 12:24'	System	04 Aug 2020 21:41:40

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:56:40**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Sherry Henning (b) (4) (b) (4)	04 Aug 2020 21:41:40

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:56:40**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'No (N)'	Sherry Henning (b) (4)	04 Aug 2020 21:41:40
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:56:40**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	04 Aug 2020 21:41:40
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:56:40**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered empty.	System	04 Aug 2020 21:41:40

US3062048

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:56:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	04 Aug 2020 21:41:59
	(b) (4)	

**US3062048**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered 'I'	System	04 Aug 2020 21:41:59

US3062048

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 18:20:39

US3062048

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:56:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-03T13:47:56', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'cfbb4a89-84b5-489b-a88e-22d5605506d0'	System	03 Aug 2020 18:48:31
User entered 'Yes (Y)'	System	03 Aug 2020 18:48:31

US3062048

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:56:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-03T13:48:11', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'cfbb4a89-84b5-489b-a88e-22d5605506d0'	System	03 Aug 2020 18:48:31
User entered '96.1'	System	03 Aug 2020 18:48:31

US3062048

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-03T13:48:17', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'cfbb4a89-84b5-489b-a88e-22d5605506d0'	System	03 Aug 2020 18:48:31
User entered 'No (N)'	System	03 Aug 2020 18:48:31

**US3062048**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-03T13:48:29', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'cfbb4a89-84b5-489b-a88e-22d5605506d0'	System	03 Aug 2020 18:48:31
User entered '03 Aug 2020 13:48'	System	03 Aug 2020 18:48:31

**US3062048**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '03 Aug 2020 13:31'	System	03 Aug 2020 18:20:39

**US3062048**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '03 Aug 2020 16:01'	System	03 Aug 2020 18:20:39

US3062048

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 18:20:39

**US3062048**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:56:40**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-03T20:55:02', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '52ae2496-a75c-48d3-8f1c-f9003d58f609'	System	04 Aug 2020 01:55:37
User entered 'Yes (Y)'	System	04 Aug 2020 01:55:37

US3062048

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:56:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-03T20:55:17', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '52ae2496-a75c-48d3-8f1c-f9003d58f609'	System	04 Aug 2020 01:55:37
User entered '95.6'	System	04 Aug 2020 01:55:37

US3062048

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-03T20:55:24', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '52ae2496-a75c-48d3-8f1c-f9003d58f609'	System	04 Aug 2020 01:55:37
User entered 'No (N)'	System	04 Aug 2020 01:55:37

**US3062048**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-03T20:55:32', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '52ae2496-a75c-48d3-8f1c-f9003d58f609'	System	04 Aug 2020 01:55:37
User entered '03 Aug 2020 20:55'	System	04 Aug 2020 01:55:37

**US3062048**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '03 Aug 2020 16:56'	System	03 Aug 2020 18:20:39

**US3062048**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 18:20:39

**US3062048**

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

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

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered 'Day 2'	System	03 Aug 2020 18:20:39

**US3062048**

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

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

**Generated On: 09 Jun 2021 14:56:40**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-04T21:02:35', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '71a68fd3-20c9-42f3-96d9-cc0f262abc66'	System	05 Aug 2020 02:02:57
User entered 'Yes (Y)'	System	05 Aug 2020 02:02:57

US3062048

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:56:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-04T21:02:43', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '71a68fd3-20c9-42f3-96d9-cc0f262abc66'	System	05 Aug 2020 02:02:57
User entered '97.6'	System	05 Aug 2020 02:02:57

US3062048

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-04T21:02:49', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '71a68fd3-20c9-42f3-96d9-cc0f262abc66'	System	05 Aug 2020 02:02:57
User entered 'No (N)'	System	05 Aug 2020 02:02:57

**US3062048**

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

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

**Generated On: 09 Jun 2021 14:56:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-04T21:02:56', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '71a68fd3-20c9-42f3-96d9-cc0f262abc66'	System	05 Aug 2020 02:02:57
User entered '04 Aug 2020 21:02'	System	05 Aug 2020 02:02:57

**US3062048**

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

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

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 18:20:39

**US3062048**

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

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

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 18:20:39

US3062048

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered 'Day 3'	System	03 Aug 2020 18:20:39

US3062048

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:56:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-05T20:20:05', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'f759bcfb-151f-4711-ba0a-11094e0fb482'	System	06 Aug 2020 01:20:48
User entered 'Yes (Y)'	System	06 Aug 2020 01:20:48

US3062048

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:56:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-05T20:20:27', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'f759bcfb-151f-4711-ba0a-11094e0fb482'	System	06 Aug 2020 01:20:48
User entered '95.7'	System	06 Aug 2020 01:20:48

US3062048

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-05T20:20:33', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'f759bcfb-151f-4711-ba0a-11094e0fb482'	System	06 Aug 2020 01:20:48
User entered 'No (N)'	System	06 Aug 2020 01:20:48

**US3062048**

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

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-05T20:20:44', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'f759bcfb-151f-4711-ba0a-11094e0fb482'	System	06 Aug 2020 01:20:48
User entered '05 Aug 2020 20:20'	System	06 Aug 2020 01:20:48

**US3062048**

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

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 18:20:39

**US3062048**

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

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 18:20:39

US3062048

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered 'Day 4'	System	03 Aug 2020 18:20:39

**US3062048**

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

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:56:40**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-06T19:19:13', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '9b4e47dd-0717-4eba-bd29-6360a0457432'	System	07 Aug 2020 00:19:45
User entered 'Yes (Y)'	System	07 Aug 2020 00:19:45

US3062048

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:56:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-06T19:19:21', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '9b4e47dd-0717-4eba-bd29-6360a0457432'	System	07 Aug 2020 00:19:45
User entered '96.8'	System	07 Aug 2020 00:19:45

US3062048

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-06T19:19:27', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '9b4e47dd-0717-4eba-bd29-6360a0457432'	System	07 Aug 2020 00:19:45
User entered 'No (N)'	System	07 Aug 2020 00:19:45

**US3062048**

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

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-06T19:19:40', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '9b4e47dd-0717-4eba-bd29-6360a0457432'	System	07 Aug 2020 00:19:45
User entered '06 Aug 2020 19:19'	System	07 Aug 2020 00:19:45

**US3062048**

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

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 18:20:39

**US3062048**

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

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 18:20:39

US3062048

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered 'Day 5'	System	03 Aug 2020 18:20:39

**US3062048**

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

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

**Generated On: 09 Jun 2021 14:56:40**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-07T21:08:58', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'a6d9b493-886b-4c83-86e8-d58cf35b65e2'	System	08 Aug 2020 02:09:32
User entered 'Yes (Y)'	System	08 Aug 2020 02:09:32

US3062048

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:56:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-07T21:09:19', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'a6d9b493-886b-4c83-86e8-d58cf35b65e2'	System	08 Aug 2020 02:09:32
User entered '97.6'	System	08 Aug 2020 02:09:32

US3062048

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-07T21:09:24', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'a6d9b493-886b-4c83-86e8-d58cf35b65e2'	System	08 Aug 2020 02:09:32
User entered 'No (N)'	System	08 Aug 2020 02:09:32

**US3062048**

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

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

**Generated On: 09 Jun 2021 14:56:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-07T21:09:31', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'a6d9b493-886b-4c83-86e8-d58cf35b65e2'	System	08 Aug 2020 02:09:32
User entered '07 Aug 2020 21:09'	System	08 Aug 2020 02:09:32

**US3062048**

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

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

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 18:20:39

**US3062048**

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

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

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 18:20:39

**US3062048**

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

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered 'Day 6'	System	03 Aug 2020 18:20:39

US3062048

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:56:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-08T19:49:57', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '88b02669-e657-4e8a-aa5f-bc5cc8d9f677'	System	09 Aug 2020 00:50:27
User entered 'Yes (Y)'	System	09 Aug 2020 00:50:27

US3062048

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:56:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-08T19:50:09', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '88b02669-e657-4e8a-aa5f-bc5cc8d9f677'	System	09 Aug 2020 00:50:27
User entered '98.6'	System	09 Aug 2020 00:50:27

US3062048

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-08T19:50:16', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '88b02669-e657-4e8a-aa5f-bc5cc8d9f677'	System	09 Aug 2020 00:50:27
User entered 'No (N)'	System	09 Aug 2020 00:50:27

**US3062048**

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

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-08T19:50:24', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '88b02669-e657-4e8a-aa5f-bc5cc8d9f677'	System	09 Aug 2020 00:50:27
User entered '08 Aug 2020 19:50'	System	09 Aug 2020 00:50:27

**US3062048**

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

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 18:20:39

**US3062048**

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

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 18:20:39

**US3062048**

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

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered 'Day 7'	System	03 Aug 2020 18:20:39

US3062048

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:56:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-09T20:29:11', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '503cdda1-74da-457c-a546-8b1113668307'	System	10 Aug 2020 01:30:06
User entered 'Yes (Y)'	System	10 Aug 2020 01:30:06

US3062048

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:56:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-09T20:29:54', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '503cdda1-74da-457c-a546-8b1113668307'	System	10 Aug 2020 01:30:06
User entered '96.1'	System	10 Aug 2020 01:30:06

US3062048

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-09T20:30:00', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '503cdda1-74da-457c-a546-8b1113668307'	System	10 Aug 2020 01:30:06
User entered 'No (N)'	System	10 Aug 2020 01:30:06

**US3062048**

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

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-09T20:30:05', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '503cdda1-74da-457c-a546-8b1113668307'	System	10 Aug 2020 01:30:06
User entered '09 Aug 2020 20:30'	System	10 Aug 2020 01:30:06

**US3062048**

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

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 18:20:39

**US3062048**

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

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 18:20:39

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 18:20:39

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:56:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-03T13:48:42', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'c903362a-c2de-4370-b71d-6c7d743adc13'	System	03 Aug 2020 18:49:07
User entered 'None (1)'	System	03 Aug 2020 18:49:07

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:56:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-03T13:48:49', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'c903362a-c2de-4370-b71d-6c7d743adc13'	System	03 Aug 2020 18:49:07
User entered 'No (N)'	System	03 Aug 2020 18:49:07

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-03T13:48:54', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'c903362a-c2de-4370-b71d-6c7d743adc13'	System	03 Aug 2020 18:49:07
User entered 'No (N)'	System	03 Aug 2020 18:49:07

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:56:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-03T13:49:00', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'c903362a-c2de-4370-b71d-6c7d743adc13'	System	03 Aug 2020 18:49:07
User entered 'None (1)'	System	03 Aug 2020 18:49:07

**US3062048**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-03T13:49:06', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'c903362a-c2de-4370-b71d-6c7d743adc13'	System	03 Aug 2020 18:49:07
User entered '03 Aug 2020 13:49'	System	03 Aug 2020 18:49:07

**US3062048**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '03 Aug 2020 13:31'	System	03 Aug 2020 18:20:39

**US3062048**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '03 Aug 2020 16:01'	System	03 Aug 2020 18:20:39

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 18:20:39

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:56:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-03T20:55:53', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'aee6a37e-34b2-48ff-aba8-5f463d400d33'	System	04 Aug 2020 01:56:28
User entered 'None (1)'	System	04 Aug 2020 01:56:28

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-03T20:55:59', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'aee6a37e-34b2-48ff-aba8-5f463d400d33'	System	04 Aug 2020 01:56:28
User entered 'No (N)'	System	04 Aug 2020 01:56:28

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-03T20:56:04', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'aee6a37e-34b2-48ff-aba8-5f463d400d33'	System	04 Aug 2020 01:56:28
User entered 'No (N)'	System	04 Aug 2020 01:56:28

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:56:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-03T20:56:22', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'aee6a37e-34b2-48ff-aba8-5f463d400d33'	System	04 Aug 2020 01:56:28
User entered 'None (1)'	System	04 Aug 2020 01:56:28

**US3062048**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-03T20:56:26', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'aee6a37e-34b2-48ff-aba8-5f463d400d33'	System	04 Aug 2020 01:56:28
User entered '03 Aug 2020 20:56'	System	04 Aug 2020 01:56:28

**US3062048**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '03 Aug 2020 16:56'	System	03 Aug 2020 18:20:39

**US3062048**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 18:20:39

**US3062048**

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

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered 'Day 2'	System	03 Aug 2020 18:20:39

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:56:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-04T21:03:33', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '1b2e69e7-829b-46ce-a15a-e2a3a6fb71d5'	System	05 Aug 2020 02:04:04
User entered 'None (1)'	System	05 Aug 2020 02:04:04

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:56:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-04T21:03:39', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '1b2e69e7-829b-46ce-a15a-e2a3a6fb71d5'	System	05 Aug 2020 02:04:04
User entered 'No (N)'	System	05 Aug 2020 02:04:04

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-04T21:03:45', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '1b2e69e7-829b-46ce-a15a-e2a3a6fb71d5'	System	05 Aug 2020 02:04:04
User entered 'No (N)'	System	05 Aug 2020 02:04:04

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:56:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-04T21:03:54', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '1b2e69e7-829b-46ce-a15a-e2a3a6fb71d5'	System	05 Aug 2020 02:04:04
User entered 'None (1)'	System	05 Aug 2020 02:04:04

**US3062048**

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

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-04T21:04:02', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '1b2e69e7-829b-46ce-a15a-e2a3a6fb71d5'	System	05 Aug 2020 02:04:04
User entered '04 Aug 2020 21:04'	System	05 Aug 2020 02:04:04

**US3062048**

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

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 18:20:39

**US3062048**

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

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 18:20:39

**US3062048**

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

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered 'Day 3'	System	03 Aug 2020 18:20:39

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:56:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-05T20:21:09', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '1370fef4-8200-496f-90b0-37e459e2a1df'	System	06 Aug 2020 01:22:08
User entered 'Does not interfere with activity (2)'	System	06 Aug 2020 01:22:08

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:56:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-05T20:21:14', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '1370fef4-8200-496f-90b0-37e459e2a1df'	System	06 Aug 2020 01:22:08
User entered 'No (N)'	System	06 Aug 2020 01:22:08

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-05T20:21:45', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '1370fef4-8200-496f-90b0-37e459e2a1df'	System	06 Aug 2020 01:22:08
User entered 'No (N)'	System	06 Aug 2020 01:22:08

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:56:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-05T20:21:57', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '1370fef4-8200-496f-90b0-37e459e2a1df'	System	06 Aug 2020 01:22:08
User entered 'None (1)'	System	06 Aug 2020 01:22:08

**US3062048**

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

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-05T20:22:05', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '1370fef4-8200-496f-90b0-37e459e2a1df'	System	06 Aug 2020 01:22:08
User entered '05 Aug 2020 20:22'	System	06 Aug 2020 01:22:08

**US3062048**

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

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 18:20:39

**US3062048**

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

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 18:20:39

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered 'Day 4'	System	03 Aug 2020 18:20:39

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:56:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-06T19:20:01', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'ec80ddec-7e34-46dc-ab45-9b5f9dfe5f21'	System	07 Aug 2020 00:20:28
User entered 'None (1)'	System	07 Aug 2020 00:20:28

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:56:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-06T19:20:06', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'ec80ddec-7e34-46dc-ab45-9b5f9dfe5f21'	System	07 Aug 2020 00:20:28
User entered 'No (N)'	System	07 Aug 2020 00:20:28

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-06T19:20:10', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'ec80ddec-7e34-46dc-ab45-9b5f9dfe5f21'	System	07 Aug 2020 00:20:28
User entered 'No (N)'	System	07 Aug 2020 00:20:28

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:56:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-06T19:20:19', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'ec80ddec-7e34-46dc-ab45-9b5f9dfe5f21'	System	07 Aug 2020 00:20:28
User entered 'None (1)'	System	07 Aug 2020 00:20:28

**US3062048**

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

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-06T19:20:24', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'ec80ddec-7e34-46dc-ab45-9b5f9dfe5f21'	System	07 Aug 2020 00:20:28
User entered '06 Aug 2020 19:20'	System	07 Aug 2020 00:20:28

**US3062048**

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

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 18:20:39

**US3062048**

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

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 18:20:39

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered 'Day 5'	System	03 Aug 2020 18:20:39

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:56:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-07T21:09:40', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '5a14ae7d-dcec-4ddb-9ad4-952ed637eec1'	System	08 Aug 2020 02:10:04
User entered 'None (1)'	System	08 Aug 2020 02:10:04

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:56:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-07T21:09:45', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '5a14ae7d-dcec-4ddb-9ad4-952ed637eec1'	System	08 Aug 2020 02:10:04
User entered 'No (N)'	System	08 Aug 2020 02:10:04

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-07T21:09:49', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '5a14ae7d-dcec-4ddb-9ad4-952ed637eec1'	System	08 Aug 2020 02:10:04
User entered 'No (N)'	System	08 Aug 2020 02:10:04

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:56:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-07T21:09:57', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '5a14ae7d-dcec-4ddb-9ad4-952ed637eec1'	System	08 Aug 2020 02:10:04
User entered 'None (1)'	System	08 Aug 2020 02:10:04

**US3062048**

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

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-07T21:10:02', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '5a14ae7d-dcec-4ddb-9ad4-952ed637eec1'	System	08 Aug 2020 02:10:04
User entered '07 Aug 2020 21:10'	System	08 Aug 2020 02:10:04

**US3062048**

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

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 18:20:39

**US3062048**

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

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 18:20:39

**US3062048**

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

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered 'Day 6'	System	03 Aug 2020 18:20:39

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:56:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-08T19:50:31', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'bbd96af1-47c9-4c01-a3b8-b014f574cff5'	System	09 Aug 2020 00:50:55
User entered 'None (1)'	System	09 Aug 2020 00:50:55

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:56:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-08T19:50:35', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'bbd96af1-47c9-4c01-a3b8-b014f574cff5'	System	09 Aug 2020 00:50:55
User entered 'No (N)'	System	09 Aug 2020 00:50:55

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-08T19:50:40', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'bbd96af1-47c9-4c01-a3b8-b014f574cff5'	System	09 Aug 2020 00:50:55
User entered 'No (N)'	System	09 Aug 2020 00:50:55

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:56:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-08T19:50:46', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'bbd96af1-47c9-4c01-a3b8-b014f574cff5'	System	09 Aug 2020 00:50:55
User entered 'None (1)'	System	09 Aug 2020 00:50:55

**US3062048**

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

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-08T19:50:52', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'bbd96af1-47c9-4c01-a3b8-b014f574cff5'	System	09 Aug 2020 00:50:55
User entered '08 Aug 2020 19:50'	System	09 Aug 2020 00:50:55

**US3062048**

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

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 18:20:39

**US3062048**

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

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 18:20:39

**US3062048**

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

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered 'Day 7'	System	03 Aug 2020 18:20:39

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:56:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-09T20:30:12', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '25edadb2-4e44-48f2-8d4b-3fcb541a7bf6'	System	10 Aug 2020 01:30:36
User entered 'None (1)'	System	10 Aug 2020 01:30:36

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:56:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-09T20:30:16', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '25edadb2-4e44-48f2-8d4b-3fcb541a7bf6'	System	10 Aug 2020 01:30:36
User entered 'No (N)'	System	10 Aug 2020 01:30:36

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-09T20:30:21', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '25edadb2-4e44-48f2-8d4b-3fcb541a7bf6'	System	10 Aug 2020 01:30:36
User entered 'No (N)'	System	10 Aug 2020 01:30:36

US3062048

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:56:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-09T20:30:31', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '25edadb2-4e44-48f2-8d4b-3fcb541a7bf6'	System	10 Aug 2020 01:30:36
User entered 'None (1)'	System	10 Aug 2020 01:30:36

**US3062048**

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

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-09T20:30:36', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '25edadb2-4e44-48f2-8d4b-3fcb541a7bf6'	System	10 Aug 2020 01:30:36
User entered '09 Aug 2020 20:30'	System	10 Aug 2020 01:30:36

**US3062048**

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

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 18:20:39

**US3062048**

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

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 18:20:39

**US3062048**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 18:20:39

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:56:40

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-03T13:49:19', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '51355dda-fbf3-4887-95c5-e67c82b159ee'	System	03 Aug 2020 18:49:49
User entered 'None (0)'	System	03 Aug 2020 18:49:49

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:56:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-03T13:49:24', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '51355dda-fbf3-4887-95c5-e67c82b159ee'	System	03 Aug 2020 18:49:49
User entered 'None (0)'	System	03 Aug 2020 18:49:49

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:56:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-03T13:49:28', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '51355dda-fbf3-4887-95c5-e67c82b159ee'	System	03 Aug 2020 18:49:49
User entered 'None (0)'	System	03 Aug 2020 18:49:49

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:56:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-03T13:49:31', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '51355dda-fbf3-4887-95c5-e67c82b159ee'	System	03 Aug 2020 18:49:49
User entered 'None (0)'	System	03 Aug 2020 18:49:49

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:56:40

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-03T13:49:34', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '51355dda-fbf3-4887-95c5-e67c82b159ee'	System	03 Aug 2020 18:49:49
User entered 'None (0)'	System	03 Aug 2020 18:49:49

**US3062048**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:56:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-03T13:49:37', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '51355dda-fbf3-4887-95c5-e67c82b159ee'	System	03 Aug 2020 18:49:49
User entered 'None (0)'	System	03 Aug 2020 18:49:49

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:56:40

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)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-03T13:49:44', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '51355dda-fbf3-4887-95c5-e67c82b159ee'	System	03 Aug 2020 18:49:49
User entered 'No (N)'	System	03 Aug 2020 18:49:49

**US3062048**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-03T13:49:48', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '51355dda-fbf3-4887-95c5-e67c82b159ee'	System	03 Aug 2020 18:49:49
User entered '03 Aug 2020 13:49'	System	03 Aug 2020 18:49:49

**US3062048**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '03 Aug 2020 13:31'	System	03 Aug 2020 18:20:39

**US3062048**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '03 Aug 2020 16:01'	System	03 Aug 2020 18:20:39

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 18:20:39

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:56:40

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-03T20:56:34', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'b188b2fd-7777-43f9-9f95-271ea954845e'	System	04 Aug 2020 01:57:09
User entered 'None (0)'	System	04 Aug 2020 01:57:09

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:56:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-03T20:56:37', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'b188b2fd-7777-43f9-9f95-271ea954845e'	System	04 Aug 2020 01:57:09
User entered 'None (0)'	System	04 Aug 2020 01:57:09

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:56:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-03T20:56:42', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'b188b2fd-7777-43f9-9f95-271ea954845e'	System	04 Aug 2020 01:57:09
User entered 'None (0)'	System	04 Aug 2020 01:57:09

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:56:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-03T20:56:46', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'b188b2fd-7777-43f9-9f95-271ea954845e'	System	04 Aug 2020 01:57:09
User entered 'None (0)'	System	04 Aug 2020 01:57:09

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:56:40

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-03T20:56:49', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'b188b2fd-7777-43f9-9f95-271ea954845e'	System	04 Aug 2020 01:57:09
User entered 'None (0)'	System	04 Aug 2020 01:57:09

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:56:40

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-03T20:56:52', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'b188b2fd-7777-43f9-9f95-271ea954845e'	System	04 Aug 2020 01:57:09
User entered 'None (0)'	System	04 Aug 2020 01:57:09

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:56:40

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)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-03T20:56:58', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'b188b2fd-7777-43f9-9f95-271ea954845e'	System	04 Aug 2020 01:57:09
User entered 'No (N)'	System	04 Aug 2020 01:57:09

**US3062048**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-03T20:57:04', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'b188b2fd-7777-43f9-9f95-271ea954845e'	System	04 Aug 2020 01:57:09
User entered '03 Aug 2020 20:57'	System	04 Aug 2020 01:57:09

**US3062048**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '03 Aug 2020 16:56'	System	03 Aug 2020 18:20:39

**US3062048**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 18:20:39

**US3062048**

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

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

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered 'Day 2'	System	03 Aug 2020 18:20:39

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:56:40

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-04T21:04:14', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'db124302-56fa-42a1-be80-38d6aaeae765'	System	05 Aug 2020 02:04:52
User entered 'None (0)'	System	05 Aug 2020 02:04:52

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:56:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-04T21:04:20', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'db124302-56fa-42a1-be80-38d6aaeae765'	System	05 Aug 2020 02:04:52
User entered 'None (0)'	System	05 Aug 2020 02:04:52

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:56:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-04T21:04:25', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'db124302-56fa-42a1-be80-38d6aaeae765'	System	05 Aug 2020 02:04:52
User entered 'None (0)'	System	05 Aug 2020 02:04:52

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:56:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-04T21:04:29', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'db124302-56fa-42a1-be80-38d6aaeae765'	System	05 Aug 2020 02:04:52
User entered 'None (0)'	System	05 Aug 2020 02:04:52

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:56:40

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-04T21:04:33', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'db124302-56fa-42a1-be80-38d6aaeae765'	System	05 Aug 2020 02:04:52
User entered 'None (0)'	System	05 Aug 2020 02:04:52

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:56:40

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-04T21:04:37', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'db124302-56fa-42a1-be80-38d6aaeae765'	System	05 Aug 2020 02:04:52
User entered 'None (0)'	System	05 Aug 2020 02:04:52

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:56:40

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)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-04T21:04:44', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'db124302-56fa-42a1-be80-38d6aaeae765'	System	05 Aug 2020 02:04:52
User entered 'No (N)'	System	05 Aug 2020 02:04:52

**US3062048**

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

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

**Generated On: 09 Jun 2021 14:56:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-04T21:04:49', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'db124302-56fa-42a1-be80-38d6aaeae765'	System	05 Aug 2020 02:04:52
User entered '04 Aug 2020 21:04'	System	05 Aug 2020 02:04:52

**US3062048**

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

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

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 18:20:39

**US3062048**

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

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

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 18:20:39

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered 'Day 3'	System	03 Aug 2020 18:20:39

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:56:40

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-05T20:22:11', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '43796144-ab63-4ab8-8b53-1a224eaa8938'	System	06 Aug 2020 01:22:43
User entered 'None (0)'	System	06 Aug 2020 01:22:43

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:56:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-05T20:22:15', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '43796144-ab63-4ab8-8b53-1a224eaa8938'	System	06 Aug 2020 01:22:43
User entered 'None (0)'	System	06 Aug 2020 01:22:43

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:56:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-05T20:22:20', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '43796144-ab63-4ab8-8b53-1a224eaa8938'	System	06 Aug 2020 01:22:43
User entered 'None (0)'	System	06 Aug 2020 01:22:43

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:56:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-05T20:22:23', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '43796144-ab63-4ab8-8b53-1a224eaa8938'	System	06 Aug 2020 01:22:43
User entered 'None (0)'	System	06 Aug 2020 01:22:43

**US3062048**

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

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:56:40**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-05T20:22:28', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '43796144-ab63-4ab8-8b53-1a224eaa8938'	System	06 Aug 2020 01:22:43
User entered 'None (0)'	System	06 Aug 2020 01:22:43

**US3062048**

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

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:56:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-05T20:22:32', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '43796144-ab63-4ab8-8b53-1a224eaa8938'	System	06 Aug 2020 01:22:43
User entered 'None (0)'	System	06 Aug 2020 01:22:43

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:56:40

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)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-05T20:22:38', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '43796144-ab63-4ab8-8b53-1a224eaa8938'	System	06 Aug 2020 01:22:43
User entered 'No (N)'	System	06 Aug 2020 01:22:43

**US3062048**

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

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-05T20:22:41', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '43796144-ab63-4ab8-8b53-1a224eaa8938'	System	06 Aug 2020 01:22:43
User entered '05 Aug 2020 20:22'	System	06 Aug 2020 01:22:43

**US3062048**

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

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 18:20:39

**US3062048**

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

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 18:20:39

**US3062048**

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

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered 'Day 4'	System	03 Aug 2020 18:20:39

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:56:40

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-06T19:20:30', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '2194c568-8289-4501-bd20-c0825b619be9'	System	07 Aug 2020 00:21:09
User entered 'None (0)'	System	07 Aug 2020 00:21:09

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:56:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-06T19:20:34', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '2194c568-8289-4501-bd20-c0825b619be9'	System	07 Aug 2020 00:21:09
User entered 'None (0)'	System	07 Aug 2020 00:21:09

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:56:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-06T19:20:39', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '2194c568-8289-4501-bd20-c0825b619be9'	System	07 Aug 2020 00:21:09
User entered 'None (0)'	System	07 Aug 2020 00:21:09

**US3062048**

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

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:56:40**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-06T19:20:44', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '2194c568-8289-4501-bd20-c0825b619be9'	System	07 Aug 2020 00:21:09
User entered 'None (0)'	System	07 Aug 2020 00:21:09

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:56:40

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-06T19:20:47', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '2194c568-8289-4501-bd20-c0825b619be9'	System	07 Aug 2020 00:21:09
User entered 'None (0)'	System	07 Aug 2020 00:21:09

**US3062048**

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

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:56:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-06T19:20:50', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '2194c568-8289-4501-bd20-c0825b619be9'	System	07 Aug 2020 00:21:09
User entered 'None (0)'	System	07 Aug 2020 00:21:09

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:56:40

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)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-06T19:21:03', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '2194c568-8289-4501-bd20-c0825b619be9'	System	07 Aug 2020 00:21:09
User entered 'No (N)'	System	07 Aug 2020 00:21:09

**US3062048**

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

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-06T19:21:07', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '2194c568-8289-4501-bd20-c0825b619be9'	System	07 Aug 2020 00:21:09
User entered '06 Aug 2020 19:21'	System	07 Aug 2020 00:21:09

**US3062048**

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

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 18:20:39

**US3062048**

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

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 18:20:39

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered 'Day 5'	System	03 Aug 2020 18:20:39

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:56:40

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-07T21:10:07', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '360e35d9-012e-4fb8-bae1-74de7c6ff3b2'	System	08 Aug 2020 02:10:40
User entered 'None (0)'	System	08 Aug 2020 02:10:40

**US3062048**

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

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

**Generated On: 09 Jun 2021 14:56:40**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-07T21:10:11', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '360e35d9-012e-4fb8-bae1-74de7c6ff3b2'	System	08 Aug 2020 02:10:40
User entered 'None (0)'	System	08 Aug 2020 02:10:40

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:56:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-07T21:10:15', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '360e35d9-012e-4fb8-bae1-74de7c6ff3b2'	System	08 Aug 2020 02:10:40
User entered 'None (0)'	System	08 Aug 2020 02:10:40

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:56:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-07T21:10:19', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '360e35d9-012e-4fb8-bae1-74de7c6ff3b2'	System	08 Aug 2020 02:10:40
User entered 'None (0)'	System	08 Aug 2020 02:10:40

**US3062048**

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

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

**Generated On: 09 Jun 2021 14:56:40**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-07T21:10:23', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '360e35d9-012e-4fb8-bae1-74de7c6ff3b2'	System	08 Aug 2020 02:10:40
User entered 'None (0)'	System	08 Aug 2020 02:10:40

**US3062048**

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

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

**Generated On: 09 Jun 2021 14:56:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-07T21:10:27', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '360e35d9-012e-4fb8-bae1-74de7c6ff3b2'	System	08 Aug 2020 02:10:40
User entered 'None (0)'	System	08 Aug 2020 02:10:40

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:56:40

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)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-07T21:10:33', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '360e35d9-012e-4fb8-bae1-74de7c6ff3b2'	System	08 Aug 2020 02:10:40
User entered 'No (N)'	System	08 Aug 2020 02:10:40

**US3062048**

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

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

**Generated On: 09 Jun 2021 14:56:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-07T21:10:37', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '360e35d9-012e-4fb8-bae1-74de7c6ff3b2'	System	08 Aug 2020 02:10:40
User entered '07 Aug 2020 21:10'	System	08 Aug 2020 02:10:40

**US3062048**

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

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

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 18:20:39

**US3062048**

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

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

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 18:20:39

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered 'Day 6'	System	03 Aug 2020 18:20:39

**US3062048**

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

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:56:40**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-08T19:50:58', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '018281ab-37ac-427b-a541-64f020576681'	System	09 Aug 2020 00:51:29
User entered 'None (0)'	System	09 Aug 2020 00:51:29

**US3062048**

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

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:56:40**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-08T19:51:01', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '018281ab-37ac-427b-a541-64f020576681'	System	09 Aug 2020 00:51:29
User entered 'None (0)'	System	09 Aug 2020 00:51:29

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:56:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-08T19:51:04', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '018281ab-37ac-427b-a541-64f020576681' User entered 'None (0)'	System	09 Aug 2020 00:51:29
	System	09 Aug 2020 00:51:29

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:56:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-08T19:51:08', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '018281ab-37ac-427b-a541-64f020576681' User entered 'None (0)'	System	09 Aug 2020 00:51:29
	System	09 Aug 2020 00:51:29

**US3062048**

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

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:56:40**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-08T19:51:11', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '018281ab-37ac-427b-a541-64f020576681'	System	09 Aug 2020 00:51:29
User entered 'None (0)'	System	09 Aug 2020 00:51:29

**US3062048**

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

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:56:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-08T19:51:14', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '018281ab-37ac-427b-a541-64f020576681'	System	09 Aug 2020 00:51:29
User entered 'None (0)'	System	09 Aug 2020 00:51:29

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:56:40

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)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-08T19:51:22', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '018281ab-37ac-427b-a541-64f020576681'	System	09 Aug 2020 00:51:29
User entered 'No (N)'	System	09 Aug 2020 00:51:29

**US3062048**

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

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-08T19:51:26', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '018281ab-37ac-427b-a541-64f020576681'	System	09 Aug 2020 00:51:29
User entered '08 Aug 2020 19:51'	System	09 Aug 2020 00:51:29

**US3062048**

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

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 18:20:39

**US3062048**

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

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 18:20:39

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered 'Day 7'	System	03 Aug 2020 18:20:39

**US3062048**

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

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:56:40**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-09T20:30:42', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '0672d96a-0f7b-4526-90c4-4d74ccefa34b'	System	10 Aug 2020 01:31:11
User entered 'None (0)'	System	10 Aug 2020 01:31:11

**US3062048**

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

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:56:40**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-09T20:30:45', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '0672d96a-0f7b-4526-90c4-4d74ccefa34b'	System	10 Aug 2020 01:31:11
User entered 'None (0)'	System	10 Aug 2020 01:31:11

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:56:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-09T20:30:49', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '0672d96a-0f7b-4526-90c4-4d74ccefa34b'	System	10 Aug 2020 01:31:11
User entered 'None (0)'	System	10 Aug 2020 01:31:11

**US3062048**

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

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:56:40**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-09T20:30:53', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '0672d96a-0f7b-4526-90c4-4d74ccefa34b'	System	10 Aug 2020 01:31:11
User entered 'None (0)'	System	10 Aug 2020 01:31:11

**US3062048**

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

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:56:40**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-09T20:30:56', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '0672d96a-0f7b-4526-90c4-4d74ccefa34b'	System	10 Aug 2020 01:31:11
User entered 'None (0)'	System	10 Aug 2020 01:31:11

**US3062048**

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

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:56:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-09T20:31:01', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '0672d96a-0f7b-4526-90c4-4d74ccefa34b'	System	10 Aug 2020 01:31:11
User entered 'None (0)'	System	10 Aug 2020 01:31:11

US3062048

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:56:40

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)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-09T20:31:06', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '0672d96a-0f7b-4526-90c4-4d74ccefa34b'	System	10 Aug 2020 01:31:11
User entered 'No (N)'	System	10 Aug 2020 01:31:11

**US3062048**

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

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-09T20:31:09', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '0672d96a-0f7b-4526-90c4-4d74ccefa34b'	System	10 Aug 2020 01:31:11
User entered '09 Aug 2020 20:31'	System	10 Aug 2020 01:31:11

**US3062048**

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

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 18:20:39

**US3062048**

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

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 18:20:39

**US3062048**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:09
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	13 Aug 2020 16:43:05
	(b) (4)	

**US3062048**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:09
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered '12 Aug 2020'	Sherry Henning (b) (4)	13 Aug 2020 16:43:05
	(b) (4)	

**US3062048**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:09
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Sherry Henning (b) (4)	13 Aug 2020 16:43:05
	(b) (4)	

**US3062048**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:09
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
User entered empty.	(b) (4) Sherry Henning (b) (4)	13 Aug 2020 16:43:05

**US3062048**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:09
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	19 Aug 2020 19:06:42
	(b) (4)	

**US3062048**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:09
User entered 'I'	System	19 Aug 2020 19:06:42

**US3062048**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:09
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	19 Aug 2020 19:07:12
	(b) (4)	

US3062048

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:40

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:09
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	19 Aug 2020 19:07:27
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	19 Aug 2020 19:07:27
User entered '18 Aug 2020' reason for change: Data Entry Error	Janna Martinez (b) (4)	19 Aug 2020 19:07:27
	(b) (4)	
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	19 Aug 2020 19:07:12
User entered '13 Aug 2020'	Janna Martinez (b) (4)	19 Aug 2020 19:07:12
	(b) (4)	

**US3062048**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:09
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Janna Martinez (b) (4)	19 Aug 2020 19:07:12
	(b) (4)	

**US3062048**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:09
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
User entered empty.	(b) (4)	19 Aug 2020 19:07:12
	Janna Martinez (b) (4)	
	(b) (4)	

US3062048

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:09
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 19:07:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Aug 2020 19:07:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Janna Martinez (b) (4)	19 Aug 2020 19:07:34
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 19:07:31
User entered empty.	Janna Martinez (b) (4)	19 Aug 2020 19:07:31
	(b) (4)	

**US3062048**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:09
User entered '1'	System	19 Aug 2020 19:07:34
User entered empty.	System	19 Aug 2020 19:07:31

**US3062048**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:09
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	26 Aug 2020 20:13:30
	(b) (4)	

**US3062048**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:09
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered '25 Aug 2020'	Janna Martinez (b) (4)	26 Aug 2020 20:13:30
	(b) (4)	

**US3062048**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:09
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Janna Martinez (b) (4)	26 Aug 2020 20:13:30
	(b) (4)	

**US3062048**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:09
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered empty.	Janna Martinez (b) (4)	26 Aug 2020 20:13:30
	(b) (4)	

**US3062048**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:09
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	26 Aug 2020 20:13:22
	(b) (4)	

**US3062048**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:09
User entered 'I'	System	26 Aug 2020 20:13:22

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:40**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'Yes (Y)'	Brianna Burton (b) (4)	31 Aug 2020 17:37:25
	(b) (4)	

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '31 Aug 2020'	Brianna Burton (b) (4)	31 Aug 2020 17:37:25
	(b) (4)	

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'Clinic (Clinic)'	Brianna Burton (b) (4)	31 Aug 2020 17:37:25
	(b) (4)	

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:40**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered 'VISIT2'	System	31 Aug 2020 17:37:25

US3062048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User accepted default value 'Pre-Dose (PREDOSE)'	Janna Martinez (b) (4)	02 Sep 2020 17:27:42
	(b) (4)	

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	02 Sep 2020 17:27:42
	(b) (4)	

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:40**

**Date of assessment (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
User entered '31 Aug 2020'	(b) (4) Janna Martinez (b) (4)	02 Sep 2020 17:27:42
	(b) (4)	

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
User entered '11:25'	(b) (4) Janna Martinez (b) (4)	02 Sep 2020 17:27:42
	(b) (4)	

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered '31 Aug 2020 11:25'	System	02 Sep 2020 17:27:42

US3062048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
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) (6)	24 Sep 2020 06:52:35
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.'	Colton King (b) (4)	23 Sep 2020 16:11:27
answered with 'NCS per PI' (Site from System).	(b) (4)	
Amendment Manager: 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	16 Sep 2020 23:41:19
User entered '96.6' F	Janna Martinez (b) (4)	02 Sep 2020 17:27:42
	(b) (4)	

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'Oral (Oral)'	Janna Martinez (b) (4)	02 Sep 2020 17:27:42
	(b) (4)	

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:40**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered empty.	Janna Martinez (b) (4)	02 Sep 2020 17:27:42
	(b) (4)	

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '64'	Janna Martinez (b) (4)	02 Sep 2020 17:27:42
	(b) (4)	

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered 'bpm'	System	02 Sep 2020 17:27:42

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '16'	Janna Martinez (b) (4)	02 Sep 2020 17:27:42
	(b) (4)	

US3062048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:56:40

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered 'breaths/min'	System	02 Sep 2020 17:27:42

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '126'	Janna Martinez (b) (4)	02 Sep 2020 17:27:42
	(b) (4)	

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered 'mmHg'	System	02 Sep 2020 17:27:42

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '78'	Janna Martinez (b) (4)	02 Sep 2020 17:27:42
	(b) (4)	

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered 'mmHg'	System	02 Sep 2020 17:27:42

US3062048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:40

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User accepted default value 'Post-Dose (POSTDOSE)'	Janna Martinez (b) (4)	02 Sep 2020 17:29:30
	(b) (4)	

US3062048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	02 Sep 2020 17:29:30
	(b) (4)	

US3062048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:40

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Sep 2020 17:29:50
User entered '31 Aug 2020' reason for change: Data Entry Error	Janna Martinez (b) (4)	02 Sep 2020 17:29:50
	(b) (4)	
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Sep 2020 17:29:30
User entered '28 Aug 2020'	Janna Martinez (b) (4)	02 Sep 2020 17:29:30
	(b) (4)	

US3062048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User closed query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	System	02 Sep 2020 17:29:50
User opened query 'Post-dose Time is prior to Pre-dose Time. Please review and reconcile.' (Site from System).	System	02 Sep 2020 17:29:30
User entered '13:05'	Janna Martinez (b) (4)	02 Sep 2020 17:29:30
	(b) (4)	

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:56:40**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered '31 Aug 2020 13:05'	System	02 Sep 2020 17:29:50
User entered '28 Aug 2020 13:05'	System	02 Sep 2020 17:29:30

US3062048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '97.9' F	Janna Martinez (b) (4)	02 Sep 2020 17:29:30
	(b) (4)	

US3062048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:40

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'Oral (Oral)'	Janna Martinez (b) (4)	02 Sep 2020 17:29:30
	(b) (4)	

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:56:40**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered empty.	Janna Martinez (b) (4)	02 Sep 2020 17:29:30
	(b) (4)	

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:56:40**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '59'	Janna Martinez (b) (4)	02 Sep 2020 17:29:30
	(b) (4)	

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:56:40**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered 'bpm'	System	02 Sep 2020 17:29:30

US3062048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '16'	Janna Martinez (b) (4)	02 Sep 2020 17:29:30
	(b) (4)	

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:56:40**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered 'breaths/min'	System	02 Sep 2020 17:29:30

US3062048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '123'	Janna Martinez (b) (4)	02 Sep 2020 17:29:30
	(b) (4)	

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:56:40**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered 'mmHg'	System	02 Sep 2020 17:29:30

US3062048

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:56:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '78'	Janna Martinez (b) (4)	02 Sep 2020 17:29:30
	(b) (4)	

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 14:56:40**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered 'mmHg'	System	02 Sep 2020 17:29:30

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:56:40**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	02 Sep 2020 17:30:05
	(b) (4)	

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:56:40**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '31 Aug 2020'	Janna Martinez (b) (4)	02 Sep 2020 17:30:05
	(b) (4)	

US3062048

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:40

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'Yes (Y)'	Brianna Burton (b) (4)	31 Aug 2020 17:37:58
	(b) (4)	

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:56:40**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered empty.	Brianna Burton (b) (4)	31 Aug 2020 17:37:58
	(b) (4)	

US3062048

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:40

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 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
User entered empty.	(b) (4) Brianna Burton (b) (4) (b) (4)	31 Aug 2020 17:37:58

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:56:40**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered 'MRNA-1273 OR PLACEBO'	System	31 Aug 2020 17:37:58

US3062048

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:40

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '31 Aug 2020'	Brianna Burton (b) (4)	31 Aug 2020 17:37:58
	(b) (4)	

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:56:40**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '12:34'	Brianna Burton (b) (4)	31 Aug 2020 17:37:58
	(b) (4)	

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:56:40**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered '31 Aug 2020 12:34'	System	31 Aug 2020 17:37:58

US3062048

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:40

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Brianna Burton (b) (4)	31 Aug 2020 17:37:58
	(b) (4)	

US3062048

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:56:40

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered 'ONCE'	System	31 Aug 2020 17:37:58

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 14:56:40**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered 'INTRAMUSCULAR'	System	31 Aug 2020 17:37:58

US3062048

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	02 Sep 2020 17:30:54
	(b) (4)	

US3062048

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:40

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 31AUG2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4)	
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 31AUG2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'V2 is correct. Site had to use unscheduled kits in place of V2 due to inadequate supply. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 17:52:47
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 31AUG2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	marissa Mueller (b) (4)	19 Oct 2020 14:34:38
User entered '31 Aug 2020'	(b) (4)	
	(b) (4), (b) (6)	19 Oct 2020 05:58:59
	Janna Martinez (b) (4)	02 Sep 2020 17:30:54
	(b) (4)	

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:56:40**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '11:30'	Janna Martinez (b) (4)	02 Sep 2020 17:30:54
	(b) (4)	

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:56:40**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered '31 Aug 2020 11:30'	System	02 Sep 2020 17:30:54

US3062048

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:56:40

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
User closed query 'Per GCL Lab Recon: GCL has an Unscheduled Swab sample with date of 31AUG2020; however, this date is recorded for Day 29 in EDC. Please confirm Day 29 is 31AUG2020 or clarify. '	(b) (4) (b) (4), (b) (6)	03 Nov 2020 23:14:43
(Site from DM). Query 'Per GCL Lab Recon: GCL has an Unscheduled Swab sample with date of 31AUG2020; however, this date is recorded for Day 29 in EDC. Please confirm Day 29 is 31AUG2020 or clarify. '	Janna Martinez (b) (4) (b) (4)	29 Oct 2020 17:46:11
answered with 'THERE WAS A SPACE BETWEEN AMENDMENTS WHERE SITE DIDNT HAVE APPROPRIATE KITS AND WAS ADVISED TO USE UNSCHEUDLED TO FULFILL NEEDED VISIT 2 LAB REQUIREMENTS.' (Site from DM). User opened query 'Per GCL Lab Recon: GCL has an Unscheduled Swab sample with date of 31AUG2020; however, this date is recorded for Day 29 in EDC. Please confirm Day 29 is 31AUG2020 or clarify. '	(b) (4), (b) (6)	24 Oct 2020 10:48:51
(Site from DM). User entered '31 Aug 2020'	Janna Martinez (b) (4) (b) (4)	02 Sep 2020 17:31:08

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Janna Martinez (b) (4)	02 Sep 2020 17:31:08
	(b) (4)	

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	02 Sep 2020 17:31:08
	(b) (4)	

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:56:40**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '11:31'	Janna Martinez (b) (4)	02 Sep 2020 17:31:08
	(b) (4)	

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered '31 Aug 2020 11:31'	System	02 Sep 2020 17:31:08

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:56:40**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Janna Martinez (b) (4)	02 Sep 2020 17:31:08
	(b) (4)	

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:56:40**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'No (N)'	Janna Martinez (b) (4)	02 Sep 2020 17:31:08
	(b) (4)	

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:56:40**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered empty.	Janna Martinez (b) (4)	02 Sep 2020 17:31:08
	(b) (4)	

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 14:56:40**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered empty.	System	02 Sep 2020 17:31:08

US3062048

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	02 Sep 2020 17:31:18
	(b) (4)	

**US3062048**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered 'I'	System	02 Sep 2020 17:31:18

US3062048

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	31 Aug 2020 17:37:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 17:37:58

US3062048

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:56:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-31T13:10:23', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '0df50c87-f309-40f8-91da-b142a5be5980'	System	31 Aug 2020 18:10:47
User entered 'Yes (Y)'	System	31 Aug 2020 18:10:47

US3062048

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:56:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-31T13:10:31', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '0df50c87-f309-40f8-91da-b142a5be5980'	System	31 Aug 2020 18:10:47
User entered '97.9'	System	31 Aug 2020 18:10:47

US3062048

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-31T13:10:37', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '0df50c87-f309-40f8-91da-b142a5be5980'	System	31 Aug 2020 18:10:47
User entered 'No (N)'	System	31 Aug 2020 18:10:47

**US3062048**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-31T13:10:42', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '0df50c87-f309-40f8-91da-b142a5be5980'	System	31 Aug 2020 18:10:47
User entered '31 Aug 2020 13:10'	System	31 Aug 2020 18:10:47

**US3062048**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '31 Aug 2020 12:54'	System	31 Aug 2020 17:37:58

**US3062048**

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

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '31 Aug 2020 15:24'	System	31 Aug 2020 17:37:58

US3062048

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	31 Aug 2020 17:37:58
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 17:37:58

**US3062048**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:56:40**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-31T19:51:22', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'a0f245cf-d282-4116-8bcd-6f22f8d5bc0c'	System	01 Sep 2020 00:51:45
User entered 'Yes (Y)'	System	01 Sep 2020 00:51:45

US3062048

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:56:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-31T19:51:30', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'a0f245cf-d282-4116-8bcd-6f22f8d5bc0c'	System	01 Sep 2020 00:51:45
User entered '97.4'	System	01 Sep 2020 00:51:45

US3062048

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-31T19:51:35', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'a0f245cf-d282-4116-8bcd-6f22f8d5bc0c'	System	01 Sep 2020 00:51:45
User entered 'No (N)'	System	01 Sep 2020 00:51:45

**US3062048**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-31T19:51:42', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'a0f245cf-d282-4116-8bcd-6f22f8d5bc0c'	System	01 Sep 2020 00:51:45
User entered '31 Aug 2020 19:51'	System	01 Sep 2020 00:51:45

**US3062048**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '31 Aug 2020 16:19'	System	31 Aug 2020 17:37:58

**US3062048**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 17:37:58

**US3062048**

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

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

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	31 Aug 2020 17:37:58
User entered 'Day 2'	System	31 Aug 2020 17:37:58

US3062048

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:56:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-01T21:07:04', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '843c0e69-e1c7-4f8c-8aa8-29ed1ca86586'	System	02 Sep 2020 02:07:48
User entered 'Yes (Y)'	System	02 Sep 2020 02:07:48

US3062048

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:56:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-01T21:07:11', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '843c0e69-e1c7-4f8c-8aa8-29ed1ca86586'	System	02 Sep 2020 02:07:48
User entered '98.6'	System	02 Sep 2020 02:07:48

US3062048

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-01T21:07:33', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '843c0e69-e1c7-4f8c-8aa8-29ed1ca86586'	System	02 Sep 2020 02:07:48
User entered 'No (N)'	System	02 Sep 2020 02:07:48

**US3062048**

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

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

**Generated On: 09 Jun 2021 14:56:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-01T21:07:40', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '843c0e69-e1c7-4f8c-8aa8-29ed1ca86586'	System	02 Sep 2020 02:07:48
User entered '01 Sep 2020 21:07'	System	02 Sep 2020 02:07:48

**US3062048**

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

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

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 17:37:58

**US3062048**

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

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

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 17:37:58

US3062048

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	31 Aug 2020 17:37:58
User entered 'Day 3'	System	31 Aug 2020 17:37:58

US3062048

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:56:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-02T20:44:31', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '9fa6f593-96f4-49bf-a90e-e6c967abf413'	System	03 Sep 2020 01:44:52
User entered 'Yes (Y)'	System	03 Sep 2020 01:44:52

US3062048

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:56:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-02T20:44:37', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '9fa6f593-96f4-49bf-a90e-e6c967abf413'	System	03 Sep 2020 01:44:52
User entered '96.7'	System	03 Sep 2020 01:44:52

US3062048

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-02T20:44:43', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '9fa6f593-96f4-49bf-a90e-e6c967abf413'	System	03 Sep 2020 01:44:52
User entered 'No (N)'	System	03 Sep 2020 01:44:52

**US3062048**

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

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-02T20:44:47', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '9fa6f593-96f4-49bf-a90e-e6c967abf413'	System	03 Sep 2020 01:44:52
User entered '02 Sep 2020 20:44'	System	03 Sep 2020 01:44:52

**US3062048**

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

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 17:37:58

**US3062048**

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

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 17:37:58

US3062048

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	31 Aug 2020 17:37:58
User entered 'Day 4'	System	31 Aug 2020 17:37:58

US3062048

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:56:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-03T23:21:59', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'bb915692-58ea-4378-91ee-12d2861525ca'	System	04 Sep 2020 04:22:19
User entered 'Yes (Y)'	System	04 Sep 2020 04:22:19

US3062048

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:56:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-03T23:22:06', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'bb915692-58ea-4378-91ee-12d2861525ca'	System	04 Sep 2020 04:22:19
User entered '96.8'	System	04 Sep 2020 04:22:19

US3062048

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-03T23:22:11', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'bb915692-58ea-4378-91ee-12d2861525ca'	System	04 Sep 2020 04:22:19
User entered 'No (N)'	System	04 Sep 2020 04:22:19

**US3062048**

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

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-03T23:22:16', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'bb915692-58ea-4378-91ee-12d2861525ca'	System	04 Sep 2020 04:22:19
User entered '03 Sep 2020 23:22'	System	04 Sep 2020 04:22:19

**US3062048**

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

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 17:37:58

**US3062048**

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

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 17:37:58

**US3062048**

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

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

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	31 Aug 2020 17:37:58
User entered 'Day 5'	System	31 Aug 2020 17:37:58

US3062048

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:56:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-04T23:56:50', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '37cb630b-0c55-4c78-8ba5-34d8916197f7'	System	05 Sep 2020 04:57:15
User entered 'Yes (Y)'	System	05 Sep 2020 04:57:15

US3062048

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:56:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-04T23:57:01', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '37cb630b-0c55-4c78-8ba5-34d8916197f7'	System	05 Sep 2020 04:57:15
User entered '96.6'	System	05 Sep 2020 04:57:15

US3062048

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-04T23:57:07', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '37cb630b-0c55-4c78-8ba5-34d8916197f7'	System	05 Sep 2020 04:57:15
User entered 'No (N)'	System	05 Sep 2020 04:57:15

**US3062048**

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

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

**Generated On: 09 Jun 2021 14:56:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-04T23:57:11', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '37cb630b-0c55-4c78-8ba5-34d8916197f7'	System	05 Sep 2020 04:57:15
User entered '04 Sep 2020 23:57'	System	05 Sep 2020 04:57:15

**US3062048**

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

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

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 17:37:58

**US3062048**

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

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

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 17:37:58

**US3062048**

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

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	31 Aug 2020 17:37:58
User entered 'Day 6'	System	31 Aug 2020 17:37:58

**US3062048**

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

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:56:40**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-05T15:09:55', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '91784893-b7a9-4f4b-9ed9-1948701b0c98'	System	05 Sep 2020 20:10:22
User entered 'Yes (Y)'	System	05 Sep 2020 20:10:22

US3062048

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:56:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-05T15:10:09', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '91784893-b7a9-4f4b-9ed9-1948701b0c98'	System	05 Sep 2020 20:10:22
User entered '96.5'	System	05 Sep 2020 20:10:22

US3062048

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-05T15:10:14', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '91784893-b7a9-4f4b-9ed9-1948701b0c98'	System	05 Sep 2020 20:10:22
User entered 'No (N)'	System	05 Sep 2020 20:10:22

**US3062048**

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

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-05T15:10:19', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '91784893-b7a9-4f4b-9ed9-1948701b0c98'	System	05 Sep 2020 20:10:22
User entered '05 Sep 2020 15:10'	System	05 Sep 2020 20:10:22

**US3062048**

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

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 17:37:58

**US3062048**

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

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 17:37:58

US3062048

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	31 Aug 2020 17:37:58
User entered 'Day 7'	System	31 Aug 2020 17:37:58

US3062048

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:56:40

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-06T12:03:48', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '6254b0f0-1399-44e9-908d-dd1052b00a6e'	System	06 Sep 2020 17:04:14
User entered 'Yes (Y)'	System	06 Sep 2020 17:04:14

US3062048

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:56:40

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-06T12:04:02', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '6254b0f0-1399-44e9-908d-dd1052b00a6e' User entered '96.7'	System	06 Sep 2020 17:04:14
	System	06 Sep 2020 17:04:14

US3062048

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-06T12:04:06', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '6254b0f0-1399-44e9-908d-dd1052b00a6e'	System	06 Sep 2020 17:04:14
User entered 'No (N)'	System	06 Sep 2020 17:04:14

**US3062048**

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

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-06T12:04:10', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '6254b0f0-1399-44e9-908d-dd1052b00a6e'	System	06 Sep 2020 17:04:14
User entered '06 Sep 2020 12:04'	System	06 Sep 2020 17:04:14

**US3062048**

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

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 17:37:58

**US3062048**

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

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 17:37:58

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	31 Aug 2020 17:37:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 17:37:58

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:56:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-31T13:11:04', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '6a7a16db-4366-467c-a595-62cdee514b0a'	System	31 Aug 2020 18:11:32
User entered 'None (1)'	System	31 Aug 2020 18:11:32

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:56:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-31T13:11:12', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '6a7a16db-4366-467c-a595-62cdee514b0a'	System	31 Aug 2020 18:11:32
User entered 'No (N)'	System	31 Aug 2020 18:11:32

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-31T13:11:15', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '6a7a16db-4366-467c-a595-62cdee514b0a'	System	31 Aug 2020 18:11:32
User entered 'No (N)'	System	31 Aug 2020 18:11:32

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 14:56:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-31T13:11:22', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '6a7a16db-4366-467c-a595-62cdee514b0a'	System	31 Aug 2020 18:11:32
User entered 'None (1)'	System	31 Aug 2020 18:11:32

**US3062048**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-31T13:11:27', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '6a7a16db-4366-467c-a595-62cdee514b0a'	System	31 Aug 2020 18:11:32
User entered '31 Aug 2020 13:11'	System	31 Aug 2020 18:11:32

**US3062048**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '31 Aug 2020 12:54'	System	31 Aug 2020 17:37:58

**US3062048**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '31 Aug 2020 15:24'	System	31 Aug 2020 17:37:58

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	31 Aug 2020 17:37:58
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 17:37:58

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:56:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-31T19:52:00', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '7630bb27-7f58-4445-a171-8f1e6dfd6c75'	System	01 Sep 2020 00:52:45
User entered 'None (1)'	System	01 Sep 2020 00:52:45

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:56:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-31T19:52:10', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '7630bb27-7f58-4445-a171-8f1e6dfd6c75'	System	01 Sep 2020 00:52:45
User entered 'No (N)'	System	01 Sep 2020 00:52:45

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-31T19:52:21', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '7630bb27-7f58-4445-a171-8f1e6dfd6c75'	System	01 Sep 2020 00:52:45
User entered 'No (N)'	System	01 Sep 2020 00:52:45

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 14:56:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-31T19:52:38', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '7630bb27-7f58-4445-a171-8f1e6dfd6c75'	System	01 Sep 2020 00:52:45
User entered 'None (1)'	System	01 Sep 2020 00:52:45

**US3062048**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-31T19:52:42', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '7630bb27-7f58-4445-a171-8f1e6dfd6c75'	System	01 Sep 2020 00:52:45
User entered '31 Aug 2020 19:52'	System	01 Sep 2020 00:52:45

**US3062048**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '31 Aug 2020 16:19'	System	31 Aug 2020 17:37:58

**US3062048**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 17:37:58

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	31 Aug 2020 17:37:58
User entered 'Day 2'	System	31 Aug 2020 17:37:58

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:56:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-01T21:07:59', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'de5f8136-9830-4649-a883-2471c8507557'	System	02 Sep 2020 02:08:25
User entered 'Does not interfere with activity (2)'	System	02 Sep 2020 02:08:25

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:56:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-01T21:08:04', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'de5f8136-9830-4649-a883-2471c8507557'	System	02 Sep 2020 02:08:25
User entered 'No (N)'	System	02 Sep 2020 02:08:25

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-01T21:08:11', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'de5f8136-9830-4649-a883-2471c8507557'	System	02 Sep 2020 02:08:25
User entered 'No (N)'	System	02 Sep 2020 02:08:25

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 14:56:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-01T21:08:18', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'de5f8136-9830-4649-a883-2471c8507557'	System	02 Sep 2020 02:08:25
User entered 'None (1)'	System	02 Sep 2020 02:08:25

**US3062048**

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

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-01T21:08:21', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'de5f8136-9830-4649-a883-2471c8507557'	System	02 Sep 2020 02:08:25
User entered '01 Sep 2020 21:08'	System	02 Sep 2020 02:08:25

**US3062048**

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

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 17:37:58

**US3062048**

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

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 17:37:58

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	31 Aug 2020 17:37:58
User entered 'Day 3'	System	31 Aug 2020 17:37:58

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:56:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-02T20:44:57', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'd62a844e-9574-448a-a14d-31d0824f1cbe'	System	03 Sep 2020 01:45:24
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 01:45:24

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:56:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-02T20:45:05', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'd62a844e-9574-448a-a14d-31d0824f1cbe'	System	03 Sep 2020 01:45:24
User entered 'No (N)'	System	03 Sep 2020 01:45:24

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-02T20:45:11', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'd62a844e-9574-448a-a14d-31d0824f1cbe'	System	03 Sep 2020 01:45:24
User entered 'No (N)'	System	03 Sep 2020 01:45:24

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 14:56:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-02T20:45:15', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'd62a844e-9574-448a-a14d-31d0824f1cbe'	System	03 Sep 2020 01:45:24
User entered 'None (1)'	System	03 Sep 2020 01:45:24

**US3062048**

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

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-02T20:45:20', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'd62a844e-9574-448a-a14d-31d0824f1cbe'	System	03 Sep 2020 01:45:24
User entered '02 Sep 2020 20:45'	System	03 Sep 2020 01:45:24

**US3062048**

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

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 17:37:58

**US3062048**

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

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 17:37:58

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	31 Aug 2020 17:37:58
User entered 'Day 4'	System	31 Aug 2020 17:37:58

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:56:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-03T23:22:21', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '04b90429-ba09-437e-a383-fb5267a1c8d1'	System	04 Sep 2020 04:22:39
User entered 'None (1)'	System	04 Sep 2020 04:22:39

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:56:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-03T23:22:25', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '04b90429-ba09-437e-a383-fb5267a1c8d1'	System	04 Sep 2020 04:22:39
User entered 'No (N)'	System	04 Sep 2020 04:22:39

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-03T23:22:28', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '04b90429-ba09-437e-a383-fb5267a1c8d1'	System	04 Sep 2020 04:22:39
User entered 'No (N)'	System	04 Sep 2020 04:22:39

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 14:56:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-03T23:22:32', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '04b90429-ba09-437e-a383-fb5267a1c8d1'	System	04 Sep 2020 04:22:39
User entered 'None (1)'	System	04 Sep 2020 04:22:39

**US3062048**

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

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-03T23:22:36', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '04b90429-ba09-437e-a383-fb5267a1c8d1'	System	04 Sep 2020 04:22:39
User entered '03 Sep 2020 23:22'	System	04 Sep 2020 04:22:39

**US3062048**

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

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 17:37:58

**US3062048**

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

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 17:37:58

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	31 Aug 2020 17:37:58
User entered 'Day 5'	System	31 Aug 2020 17:37:58

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:56:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-04T23:55:36', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '5f9e0885-a060-4a0d-9ab3-733cc3c2e199'	System	05 Sep 2020 04:55:58
User entered 'None (1)'	System	05 Sep 2020 04:55:58

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:56:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-04T23:55:41', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '5f9e0885-a060-4a0d-9ab3-733cc3c2e199'	System	05 Sep 2020 04:55:58
User entered 'No (N)'	System	05 Sep 2020 04:55:58

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-04T23:55:44', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '5f9e0885-a060-4a0d-9ab3-733cc3c2e199'	System	05 Sep 2020 04:55:58
User entered 'No (N)'	System	05 Sep 2020 04:55:58

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 14:56:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-04T23:55:50', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '5f9e0885-a060-4a0d-9ab3-733cc3c2e199'	System	05 Sep 2020 04:55:58
User entered 'None (1)'	System	05 Sep 2020 04:55:58

**US3062048**

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

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-04T23:55:54', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '5f9e0885-a060-4a0d-9ab3-733cc3c2e199'	System	05 Sep 2020 04:55:58
User entered '04 Sep 2020 23:55'	System	05 Sep 2020 04:55:58

**US3062048**

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

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 17:37:58

**US3062048**

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

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 17:37:58

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	31 Aug 2020 17:37:58
User entered 'Day 6'	System	31 Aug 2020 17:37:58

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:56:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-05T15:10:24', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '3eb5d589-97f9-431c-82e6-d14fe9ecddc8'	System	05 Sep 2020 20:10:44
User entered 'None (1)'	System	05 Sep 2020 20:10:44

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:56:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-05T15:10:27', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '3eb5d589-97f9-431c-82e6-d14fe9ecddc8'	System	05 Sep 2020 20:10:44
User entered 'No (N)'	System	05 Sep 2020 20:10:44

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-05T15:10:31', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '3eb5d589-97f9-431c-82e6-d14fe9ecddc8'	System	05 Sep 2020 20:10:44
User entered 'No (N)'	System	05 Sep 2020 20:10:44

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 14:56:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-05T15:10:37', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '3eb5d589-97f9-431c-82e6-d14fe9ecddc8'	System	05 Sep 2020 20:10:44
User entered 'None (1)'	System	05 Sep 2020 20:10:44

**US3062048**

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

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-05T15:10:42', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '3eb5d589-97f9-431c-82e6-d14fe9ecddc8'	System	05 Sep 2020 20:10:44
User entered '05 Sep 2020 15:10'	System	05 Sep 2020 20:10:44

**US3062048**

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

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 17:37:58

**US3062048**

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

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 17:37:58

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	31 Aug 2020 17:37:58
User entered 'Day 7'	System	31 Aug 2020 17:37:58

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:56:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-06T12:04:16', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '88dc55e1-2170-43c2-8bfc-673c2a71e82c'	System	06 Sep 2020 17:04:39
User entered 'None (1)'	System	06 Sep 2020 17:04:39

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:56:40

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-06T12:04:20', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '88dc55e1-2170-43c2-8bfc-673c2a71e82c'	System	06 Sep 2020 17:04:39
User entered 'No (N)'	System	06 Sep 2020 17:04:39

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:56:40

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-06T12:04:24', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '88dc55e1-2170-43c2-8bfc-673c2a71e82c'	System	06 Sep 2020 17:04:39
User entered 'No (N)'	System	06 Sep 2020 17:04:39

US3062048

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 14:56:40

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-06T12:04:29', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '88dc55e1-2170-43c2-8bfc-673c2a71e82c'	System	06 Sep 2020 17:04:39
User entered 'None (1)'	System	06 Sep 2020 17:04:39

**US3062048**

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

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-06T12:04:33', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '88dc55e1-2170-43c2-8bfc-673c2a71e82c'	System	06 Sep 2020 17:04:39
User entered '06 Sep 2020 12:04'	System	06 Sep 2020 17:04:39

**US3062048**

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

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 17:37:58

**US3062048**

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

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 17:37:58

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	31 Aug 2020 17:37:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 17:37:58

**US3062048**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:56:40**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-31T13:11:32', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'bc4607a6-92e4-45bd-9bc9-6baa356cdff9'	System	31 Aug 2020 18:12:01
User entered 'None (0)'	System	31 Aug 2020 18:12:01

**US3062048**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:56:40**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-31T13:11:35', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'bc4607a6-92e4-45bd-9bc9-6baa356cdff9'	System	31 Aug 2020 18:12:01
User entered 'None (0)'	System	31 Aug 2020 18:12:01

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:56:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-31T13:11:38', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'bc4607a6-92e4-45bd-9bc9-6baa356cdf9'	System	31 Aug 2020 18:12:01
User entered 'None (0)'	System	31 Aug 2020 18:12:01

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:56:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-31T13:11:41', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'bc4607a6-92e4-45bd-9bc9-6baa356cdff9'	System	31 Aug 2020 18:12:01
User entered 'None (0)'	System	31 Aug 2020 18:12:01

**US3062048**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:56:40**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-31T13:11:44', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'bc4607a6-92e4-45bd-9bc9-6baa356cdff9'	System	31 Aug 2020 18:12:01
User entered 'None (0)'	System	31 Aug 2020 18:12:01

**US3062048**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:56:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-31T13:11:47', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'bc4607a6-92e4-45bd-9bc9-6baa356cdff9'	System	31 Aug 2020 18:12:01
User entered 'None (0)'	System	31 Aug 2020 18:12:01

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 14:56:40

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)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-31T13:11:53', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'bc4607a6-92e4-45bd-9bc9-6baa356cdff9'	System	31 Aug 2020 18:12:01
User entered 'No (N)'	System	31 Aug 2020 18:12:01

**US3062048**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-31T13:11:57', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'bc4607a6-92e4-45bd-9bc9-6baa356cdff9'	System	31 Aug 2020 18:12:01
User entered '31 Aug 2020 13:11'	System	31 Aug 2020 18:12:01

**US3062048**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '31 Aug 2020 12:54'	System	31 Aug 2020 17:37:58

**US3062048**

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

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '31 Aug 2020 15:24'	System	31 Aug 2020 17:37:58

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	31 Aug 2020 17:37:58
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 17:37:58

**US3062048**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:56:40**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-31T19:52:50', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '5f731def-b71c-410d-85ab-76a72d21be36'	System	01 Sep 2020 00:53:51
User entered 'None (0)'	System	01 Sep 2020 00:53:51

**US3062048**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:56:40**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-31T19:52:55', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '5f731def-b71c-410d-85ab-76a72d21be36'	System	01 Sep 2020 00:53:51
User entered 'None (0)'	System	01 Sep 2020 00:53:51

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:56:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-31T19:53:23', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '5f731def-b71c-410d-85ab-76a72d21be36'	System	01 Sep 2020 00:53:51
User entered 'No interference with activity (1)'	System	01 Sep 2020 00:53:51

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:56:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-31T19:53:29', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '5f731def-b71c-410d-85ab-76a72d21be36'	System	01 Sep 2020 00:53:51
User entered 'No interference with activity (1)'	System	01 Sep 2020 00:53:51

**US3062048**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:56:40**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-31T19:53:32', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '5f731def-b71c-410d-85ab-76a72d21be36'	System	01 Sep 2020 00:53:51
User entered 'None (0)'	System	01 Sep 2020 00:53:51

**US3062048**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:56:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-31T19:53:38', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '5f731def-b71c-410d-85ab-76a72d21be36'	System	01 Sep 2020 00:53:51
User entered 'None (0)'	System	01 Sep 2020 00:53:51

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 14:56:40

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)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-31T19:53:45', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '5f731def-b71c-410d-85ab-76a72d21be36'	System	01 Sep 2020 00:53:51
User entered 'No (N)'	System	01 Sep 2020 00:53:51

**US3062048**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-08-31T19:53:49', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '5f731def-b71c-410d-85ab-76a72d21be36'	System	01 Sep 2020 00:53:51
User entered '31 Aug 2020 19:53'	System	01 Sep 2020 00:53:51

**US3062048**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '31 Aug 2020 16:19'	System	31 Aug 2020 17:37:58

**US3062048**

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

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 17:37:58

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	31 Aug 2020 17:37:58
User entered 'Day 2'	System	31 Aug 2020 17:37:58

**US3062048**

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

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

**Generated On: 09 Jun 2021 14:56:40**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-01T21:08:29', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'ab66dd9b-b4b5-401c-a17d-52b16bc7eb74'	System	02 Sep 2020 02:09:32
User entered 'None (0)'	System	02 Sep 2020 02:09:32

**US3062048**

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

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

**Generated On: 09 Jun 2021 14:56:40**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-01T21:08:39', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'ab66dd9b-b4b5-401c-a17d-52b16bc7eb74'	System	02 Sep 2020 02:09:32
User entered 'None (0)'	System	02 Sep 2020 02:09:32

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:56:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-01T21:08:44', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'ab66dd9b-b4b5-401c-a17d-52b16bc7eb74'	System	02 Sep 2020 02:09:32
User entered 'None (0)'	System	02 Sep 2020 02:09:32

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:56:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-01T21:09:14', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'ab66dd9b-b4b5-401c-a17d-52b16bc7eb74'	System	02 Sep 2020 02:09:32
User entered 'None (0)'	System	02 Sep 2020 02:09:32

**US3062048**

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

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

**Generated On: 09 Jun 2021 14:56:40**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-01T21:09:19', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'ab66dd9b-b4b5-401c-a17d-52b16bc7eb74'	System	02 Sep 2020 02:09:32
User entered 'None (0)'	System	02 Sep 2020 02:09:32

**US3062048**

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

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

**Generated On: 09 Jun 2021 14:56:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-01T21:09:21', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'ab66dd9b-b4b5-401c-a17d-52b16bc7eb74'	System	02 Sep 2020 02:09:32
User entered 'None (0)'	System	02 Sep 2020 02:09:32

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 14:56:40

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)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-01T21:09:25', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'ab66dd9b-b4b5-401c-a17d-52b16bc7eb74'	System	02 Sep 2020 02:09:32
User entered 'No (N)'	System	02 Sep 2020 02:09:32

**US3062048**

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

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

**Generated On: 09 Jun 2021 14:56:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-01T21:09:28', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'ab66dd9b-b4b5-401c-a17d-52b16bc7eb74'	System	02 Sep 2020 02:09:32
User entered '01 Sep 2020 21:09'	System	02 Sep 2020 02:09:32

**US3062048**

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

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

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 17:37:58

**US3062048**

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

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

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 17:37:58

**US3062048**

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

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	31 Aug 2020 17:37:58
User entered 'Day 3'	System	31 Aug 2020 17:37:58

**US3062048**

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

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:56:40**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-02T20:45:26', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'dfe35597-b9c3-46b6-8cb9-11bd04aa69d0'	System	03 Sep 2020 01:45:51
User entered 'None (0)'	System	03 Sep 2020 01:45:51

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:56:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-02T20:45:29', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'dfe35597-b9c3-46b6-8cb9-11bd04aa69d0'	System	03 Sep 2020 01:45:51
User entered 'None (0)'	System	03 Sep 2020 01:45:51

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:56:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-02T20:45:31', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'dfe35597-b9c3-46b6-8cb9-11bd04aa69d0'	System	03 Sep 2020 01:45:51
User entered 'None (0)'	System	03 Sep 2020 01:45:51

**US3062048**

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

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:56:40**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-02T20:45:34', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'dfe35597-b9c3-46b6-8cb9-11bd04aa69d0'	System	03 Sep 2020 01:45:51
User entered 'None (0)'	System	03 Sep 2020 01:45:51

**US3062048**

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

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:56:40**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-02T20:45:37', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'dfe35597-b9c3-46b6-8cb9-11bd04aa69d0'	System	03 Sep 2020 01:45:51
User entered 'None (0)'	System	03 Sep 2020 01:45:51

**US3062048**

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

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:56:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-02T20:45:39', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'dfe35597-b9c3-46b6-8cb9-11bd04aa69d0'	System	03 Sep 2020 01:45:51
User entered 'None (0)'	System	03 Sep 2020 01:45:51

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 14:56:40

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)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-02T20:45:42', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'dfe35597-b9c3-46b6-8cb9-11bd04aa69d0'	System	03 Sep 2020 01:45:51
User entered 'No (N)'	System	03 Sep 2020 01:45:51

**US3062048**

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

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-02T20:45:45', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'dfe35597-b9c3-46b6-8cb9-11bd04aa69d0'	System	03 Sep 2020 01:45:51
User entered '02 Sep 2020 20:45'	System	03 Sep 2020 01:45:51

**US3062048**

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

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 17:37:58

**US3062048**

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

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 17:37:58

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	31 Aug 2020 17:37:58
User entered 'Day 4'	System	31 Aug 2020 17:37:58

**US3062048**

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

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:56:40**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-03T23:22:41', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'e5b62579-9a64-49c3-ac53-84692aa53717'	System	04 Sep 2020 04:23:07
User entered 'None (0)'	System	04 Sep 2020 04:23:07

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:56:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-03T23:22:45', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'e5b62579-9a64-49c3-ac53-84692aa53717'	System	04 Sep 2020 04:23:07
User entered 'None (0)'	System	04 Sep 2020 04:23:07

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:56:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-03T23:22:48', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'e5b62579-9a64-49c3-ac53-84692aa53717'	System	04 Sep 2020 04:23:07
User entered 'None (0)'	System	04 Sep 2020 04:23:07

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:56:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-03T23:22:51', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'e5b62579-9a64-49c3-ac53-84692aa53717'	System	04 Sep 2020 04:23:07
User entered 'None (0)'	System	04 Sep 2020 04:23:07

**US3062048**

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

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:56:40**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-03T23:22:54', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'e5b62579-9a64-49c3-ac53-84692aa53717'	System	04 Sep 2020 04:23:07
User entered 'None (0)'	System	04 Sep 2020 04:23:07

**US3062048**

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

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:56:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-03T23:22:57', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'e5b62579-9a64-49c3-ac53-84692aa53717'	System	04 Sep 2020 04:23:07
User entered 'None (0)'	System	04 Sep 2020 04:23:07

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 14:56:40

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)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-03T23:23:01', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'e5b62579-9a64-49c3-ac53-84692aa53717'	System	04 Sep 2020 04:23:07
User entered 'No (N)'	System	04 Sep 2020 04:23:07

**US3062048**

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

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-03T23:23:03', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'e5b62579-9a64-49c3-ac53-84692aa53717'	System	04 Sep 2020 04:23:07
User entered '03 Sep 2020 23:23'	System	04 Sep 2020 04:23:07

**US3062048**

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

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 17:37:58

**US3062048**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 17:37:58

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:56:40

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	31 Aug 2020 17:37:58
User entered 'Day 5'	System	31 Aug 2020 17:37:58

**US3062048**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:56:40**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-04T23:56:00', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '36684ca9-78c0-4bed-b7ba-a1b544614077'	System	05 Sep 2020 04:56:35
User entered 'None (0)'	System	05 Sep 2020 04:56:35

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:56:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-04T23:56:05', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '36684ca9-78c0-4bed-b7ba-a1b544614077'	System	05 Sep 2020 04:56:35
User entered 'None (0)'	System	05 Sep 2020 04:56:35

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:56:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-04T23:56:09', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '36684ca9-78c0-4bed-b7ba-a1b544614077'	System	05 Sep 2020 04:56:35
User entered 'None (0)'	System	05 Sep 2020 04:56:35

**US3062048**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:56:40**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-04T23:56:13', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '36684ca9-78c0-4bed-b7ba-a1b544614077'	System	05 Sep 2020 04:56:35
User entered 'None (0)'	System	05 Sep 2020 04:56:35

**US3062048**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:56:40**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-04T23:56:17', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '36684ca9-78c0-4bed-b7ba-a1b544614077'	System	05 Sep 2020 04:56:35
User entered 'None (0)'	System	05 Sep 2020 04:56:35

**US3062048**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:56:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-04T23:56:21', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '36684ca9-78c0-4bed-b7ba-a1b544614077'	System	05 Sep 2020 04:56:35
User entered 'None (0)'	System	05 Sep 2020 04:56:35

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 14:56:40

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)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-04T23:56:27', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '36684ca9-78c0-4bed-b7ba-a1b544614077'	System	05 Sep 2020 04:56:35
User entered 'No (N)'	System	05 Sep 2020 04:56:35

**US3062048**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-04T23:56:32', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '36684ca9-78c0-4bed-b7ba-a1b544614077'	System	05 Sep 2020 04:56:35
User entered '04 Sep 2020 23:56'	System	05 Sep 2020 04:56:35

**US3062048**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 17:37:58

**US3062048**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 17:37:58

**US3062048**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	31 Aug 2020 17:37:58
User entered 'Day 6'	System	31 Aug 2020 17:37:58

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:56:40

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-05T15:10:47', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'adb76707-e967-4fb8-bd7d-e51ef909dad5'	System	05 Sep 2020 20:11:14
User entered 'None (0)'	System	05 Sep 2020 20:11:14

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:56:40

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-05T15:10:50', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'adb76707-e967-4fb8-bd7d-e51ef909dad5'	System	05 Sep 2020 20:11:14
User entered 'None (0)'	System	05 Sep 2020 20:11:14

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:56:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-05T15:10:53', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'adb76707-e967-4fb8-bd7d-e51ef909dad5'	System	05 Sep 2020 20:11:14
User entered 'None (0)'	System	05 Sep 2020 20:11:14

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:56:40

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-05T15:10:56', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'adb76707-e967-4fb8-bd7d-e51ef909dad5'	System	05 Sep 2020 20:11:14
User entered 'None (0)'	System	05 Sep 2020 20:11:14

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:56:40

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-05T15:10:58', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'adb76707-e967-4fb8-bd7d-e51ef909dad5'	System	05 Sep 2020 20:11:14
User entered 'None (0)'	System	05 Sep 2020 20:11:14

**US3062048**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:56:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-05T15:11:02', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'adb76707-e967-4fb8-bd7d-e51ef909dad5'	System	05 Sep 2020 20:11:14
User entered 'None (0)'	System	05 Sep 2020 20:11:14

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 14:56:40

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)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-05T15:11:06', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'adb76707-e967-4fb8-bd7d-e51ef909dad5'	System	05 Sep 2020 20:11:14
User entered 'No (N)'	System	05 Sep 2020 20:11:14

**US3062048**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-05T15:11:09', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'adb76707-e967-4fb8-bd7d-e51ef909dad5'	System	05 Sep 2020 20:11:14
User entered '05 Sep 2020 15:11'	System	05 Sep 2020 20:11:14

**US3062048**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 17:37:58

**US3062048**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 17:37:58

**US3062048**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	31 Aug 2020 17:37:58
User entered 'Day 7'	System	31 Aug 2020 17:37:58

**US3062048**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:56:40**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-06T12:04:38', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '86af6945-fcac-43cc-b393-43d3b626b5f7'	System	06 Sep 2020 17:05:01
User entered 'None (0)'	System	06 Sep 2020 17:05:01

**US3062048**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:56:40**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-06T12:04:41', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '86af6945-fcac-43cc-b393-43d3b626b5f7'	System	06 Sep 2020 17:05:01
User entered 'None (0)'	System	06 Sep 2020 17:05:01

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:56:40

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-06T12:04:43', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '86af6945-fcac-43cc-b393-43d3b626b5f7'	System	06 Sep 2020 17:05:01
User entered 'None (0)'	System	06 Sep 2020 17:05:01

**US3062048**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:56:40**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-06T12:04:46', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '86af6945-fcac-43cc-b393-43d3b626b5f7'	System	06 Sep 2020 17:05:01
User entered 'None (0)'	System	06 Sep 2020 17:05:01

**US3062048**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:56:40**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-06T12:04:49', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '86af6945-fcac-43cc-b393-43d3b626b5f7'	System	06 Sep 2020 17:05:01
User entered 'None (0)'	System	06 Sep 2020 17:05:01

**US3062048**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:56:40**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-06T12:04:52', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '86af6945-fcac-43cc-b393-43d3b626b5f7'	System	06 Sep 2020 17:05:01
User entered 'None (0)'	System	06 Sep 2020 17:05:01

US3062048

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 14:56:40

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)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-06T12:04:55', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '86af6945-fcac-43cc-b393-43d3b626b5f7'	System	06 Sep 2020 17:05:01
User entered 'No (N)'	System	06 Sep 2020 17:05:01

**US3062048**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-09-06T12:04:58', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '86af6945-fcac-43cc-b393-43d3b626b5f7'	System	06 Sep 2020 17:05:01
User entered '06 Sep 2020 12:04'	System	06 Sep 2020 17:05:01

**US3062048**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 17:37:58

**US3062048**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 14:56:40**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 17:37:58

**US3062048**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:09
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4) (b) (4)	09 Sep 2020 14:55:07

**US3062048**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:09
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered '8 Sep 2020'	Colton King (b) (4)	09 Sep 2020 14:55:07
	(b) (4)	

**US3062048**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:09
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Colton King (b) (4) (b) (4)	09 Sep 2020 14:55:07

**US3062048**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:09
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
User entered empty.	(b) (4) Colton King (b) (4)	09 Sep 2020 14:55:07

**US3062048**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:09
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	09 Sep 2020 14:55:11
	(b) (4)	

**US3062048**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:09
User entered 'I'	System	09 Sep 2020 14:55:11

**US3062048**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:09
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4) (b) (4)	14 Sep 2020 16:32:10

**US3062048**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:09
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered '14 Sep 2020'	Colton King (b) (4)	14 Sep 2020 16:32:10
	(b) (4)	

**US3062048**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:09
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Colton King (b) (4) (b) (4)	14 Sep 2020 16:32:10

**US3062048**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:09
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered empty.	Colton King (b) (4)	14 Sep 2020 16:32:10
	(b) (4)	

**US3062048**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:09
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4) (b) (4)	14 Sep 2020 16:32:13

**US3062048**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:09
User entered 'I'	System	14 Sep 2020 16:32:13

**US3062048**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:09
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	22 Sep 2020 21:48:46
	(b) (4)	

**US3062048**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:09
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered '22 Sep 2020'	Colton King (b) (4)	22 Sep 2020 21:48:46
	(b) (4)	

**US3062048**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:09
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Colton King (b) (4)	22 Sep 2020 21:48:46
	(b) (4)	

US3062048

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:40

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:09
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
User entered empty.	(b) (4) Colton King (b) (4)	22 Sep 2020 21:48:46

**US3062048**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:09
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:17:49
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	22 Sep 2020 21:48:59
	(b) (4)	

**US3062048**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:09
User entered 'I'	System	22 Sep 2020 21:48:59

**US3062048**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:40**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	26 Sep 2020 19:10:22
	(b) (4)	

**US3062048**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:40**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '26 Sep 2020'	Janna Martinez (b) (4)	26 Sep 2020 19:10:22
	(b) (4)	

**US3062048**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:40**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'Home (Home)'	Janna Martinez (b) (4)	26 Sep 2020 19:10:22
	(b) (4)	

**US3062048**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:40**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered 'VISIT3'	System	26 Sep 2020 19:10:22

**US3062048**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	26 Sep 2020 19:10:47
	(b) (4)	

US3062048

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '26 Sep 2020'	Janna Martinez (b) (4)	26 Sep 2020 19:10:47
	(b) (4)	

**US3062048**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '08:03'	Janna Martinez (b) (4)	26 Sep 2020 19:10:47
	(b) (4)	

**US3062048**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered '26 Sep 2020 08:03'	System	26 Sep 2020 19:10:47

**US3062048**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '98.3' F	Janna Martinez (b) (4)	26 Sep 2020 19:10:47
	(b) (4)	

**US3062048**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'Oral (Oral)'	Janna Martinez (b) (4)	26 Sep 2020 19:10:47
	(b) (4)	

**US3062048**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
User entered empty.	(b) (4) Janna Martinez (b) (4)	26 Sep 2020 19:10:47
	(b) (4)	

**US3062048**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '67'	Janna Martinez (b) (4)	26 Sep 2020 19:10:47
	(b) (4)	

**US3062048**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered 'bpm'	System	26 Sep 2020 19:10:47

**US3062048**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
User entered '16'	(b) (4) Janna Martinez (b) (4)	26 Sep 2020 19:10:47
	(b) (4)	

**US3062048**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered 'breaths/min'	System	26 Sep 2020 19:10:47

**US3062048**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '135'	Janna Martinez (b) (4)	26 Sep 2020 19:10:47
	(b) (4)	

**US3062048**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered 'mmHg'	System	26 Sep 2020 19:10:47

**US3062048**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '73'	Janna Martinez (b) (4)	26 Sep 2020 19:10:47
	(b) (4)	

**US3062048**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered 'mmHg'	System	26 Sep 2020 19:10:47

**US3062048**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Mar 2021 00:48:24

**US3062048**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Mar 2021 00:48:24

US3062048

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'No (N)'	Janna Martinez (b) (4)	26 Sep 2020 19:10:51
	(b) (4)	

US3062048

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:40

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered empty.	Janna Martinez (b) (4)	26 Sep 2020 19:10:51
	(b) (4)	

**US3062048**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:56:40**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	26 Sep 2020 19:11:03
	(b) (4)	

**US3062048**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:56:40**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '26 Sep 2020'	Janna Martinez (b) (4)	26 Sep 2020 19:11:03
	(b) (4)	

**US3062048**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:56:40**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered '08:14'	Janna Martinez (b) (4)	26 Sep 2020 19:11:03
	(b) (4)	

**US3062048**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:56:40**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered '26 Sep 2020 08:14'	System	26 Sep 2020 19:11:03

**US3062048**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Feb 2021 15:18:07
	(b) (4)	
User entered 'Yes (Y)'	Janna Martinez (b) (4)	26 Sep 2020 19:09:58
	(b) (4)	

**US3062048**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered 'I'	System	26 Sep 2020 19:09:58

**US3062048**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered 'Day 64'	System	03 Aug 2020 18:20:39

**US3062048**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[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)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-10-04T17:26:59', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'd01de70e-bc39-4132-953b-148e45fd04a5'	System	04 Oct 2020 22:27:21
User entered 'No (N)'	System	04 Oct 2020 22:27:21

US3062048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

Have you been exposed to someone with 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)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-10-04T17:27:11', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'd01de70e-bc39-4132-953b-148e45fd04a5'	System	04 Oct 2020 22:27:21
User entered 'No (N)'	System	04 Oct 2020 22:27:21

**US3062048**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-10-04T17:27:16', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'd01de70e-bc39-4132-953b-148e45fd04a5'	System	04 Oct 2020 22:27:21
User entered '04 Oct 2020 17:27:16'	System	04 Oct 2020 22:27:21

**US3062048**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered '03 Oct 2020 00:01'	System	03 Aug 2020 18:20:39

**US3062048**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered '07 Oct 2020 23:59'	System	03 Aug 2020 18:20:39

**US3062048**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered 'Day 71'	System	03 Aug 2020 18:20:39

US3062048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

[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)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-10-11T15:48:43', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'cce5674a-19b4-4255-b5ea-a7d965e8d6e1'	System	11 Oct 2020 20:49:04
User entered 'No (N)'	System	11 Oct 2020 20:49:04

US3062048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

Have you been exposed to someone with 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)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-10-11T15:48:55', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'cce5674a-19b4-4255-b5ea-a7d965e8d6e1'	System	11 Oct 2020 20:49:04
User entered 'No (N)'	System	11 Oct 2020 20:49:04

**US3062048**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-10-11T15:49:02', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'cce5674a-19b4-4255-b5ea-a7d965e8d6e1'	System	11 Oct 2020 20:49:04
User entered '11 Oct 2020 15:49:02'	System	11 Oct 2020 20:49:04

**US3062048**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered '10 Oct 2020 00:01'	System	03 Aug 2020 18:20:39

**US3062048**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered '14 Oct 2020 23:59'	System	03 Aug 2020 18:20:39

**US3062048**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered 'Day 78'	System	03 Aug 2020 18:20:39

**US3062048**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[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)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-10-19T06:10:04', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '551171e9-fe96-43cc-8001-ca211f909bf5'	System	19 Oct 2020 11:10:21
User entered 'No (N)'	System	19 Oct 2020 11:10:21

US3062048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

Have you been exposed to someone with 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)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-10-19T06:10:13', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '551171e9-fe96-43cc-8001-ca211f909bf5'	System	19 Oct 2020 11:10:21
User entered 'No (N)'	System	19 Oct 2020 11:10:21

**US3062048**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-10-19T06:10:19', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '551171e9-fe96-43cc-8001-ca211f909bf5'	System	19 Oct 2020 11:10:21
User entered '19 Oct 2020 06:10:19'	System	19 Oct 2020 11:10:21

**US3062048**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered '17 Oct 2020 00:01'	System	03 Aug 2020 18:20:39

**US3062048**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered '21 Oct 2020 23:59'	System	03 Aug 2020 18:20:39

**US3062048**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered 'Day 92'	System	03 Aug 2020 18:20:39

US3062048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

[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)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-11-01T19:39:34', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '7bec6b58-4ef9-41ed-8397-6513c7c3e145'	System	02 Nov 2020 01:40:01
User entered 'No (N)'	System	02 Nov 2020 01:40:01

US3062048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

Have you been exposed to someone with 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)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-11-01T19:39:48', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '7bec6b58-4ef9-41ed-8397-6513c7c3e145'	System	02 Nov 2020 01:40:01
User entered 'No (N)'	System	02 Nov 2020 01:40:01

**US3062048**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-11-01T19:39:56', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '7bec6b58-4ef9-41ed-8397-6513c7c3e145'	System	02 Nov 2020 01:40:01
User entered '01 Nov 2020 19:39:56'	System	02 Nov 2020 01:40:01

**US3062048**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered '31 Oct 2020 00:01'	System	03 Aug 2020 18:20:39

**US3062048**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered '04 Nov 2020 23:59'	System	03 Aug 2020 18:20:39

**US3062048**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered 'Day 99'	System	03 Aug 2020 18:20:39

US3062048

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:56:40

[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)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-11-09T10:08:36', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '9b3eebab-90b3-4c79-bb2a-209645d6b48b'	System	09 Nov 2020 16:08:52
User entered 'No (N)'	System	09 Nov 2020 16:08:52

**US3062048**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Have you been exposed to someone with 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)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-11-09T10:08:44', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '9b3eebab-90b3-4c79-bb2a-209645d6b48b'	System	09 Nov 2020 16:08:52
User entered 'No (N)'	System	09 Nov 2020 16:08:52

**US3062048**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-11-09T10:08:47', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '9b3eebab-90b3-4c79-bb2a-209645d6b48b'	System	09 Nov 2020 16:08:52
User entered '09 Nov 2020 10:08:47'	System	09 Nov 2020 16:08:52

**US3062048**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered '07 Nov 2020 00:01'	System	03 Aug 2020 18:20:39

**US3062048**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered '11 Nov 2020 23:59'	System	03 Aug 2020 18:20:39

**US3062048**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered 'Day 106'	System	03 Aug 2020 18:20:39

**US3062048**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[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)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-11-16T07:06:20', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '0bb9805d-2744-40a7-b054-1f7d45e5b11f'	System	16 Nov 2020 13:06:40
User entered 'No (N)'	System	16 Nov 2020 13:06:40

**US3062048**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Have you been exposed to someone with 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)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-11-16T07:06:35', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '0bb9805d-2744-40a7-b054-1f7d45e5b11f'	System	16 Nov 2020 13:06:40
User entered 'No (N)'	System	16 Nov 2020 13:06:40

**US3062048**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-11-16T07:06:39', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '0bb9805d-2744-40a7-b054-1f7d45e5b11f' User entered '16 Nov 2020 07:06:39'	System	16 Nov 2020 13:06:40
	System	16 Nov 2020 13:06:40

**US3062048**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered '14 Nov 2020 00:01'	System	03 Aug 2020 18:20:39

**US3062048**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:33:49
Data entry locked.	System	03 Aug 2020 18:20:39
User entered '18 Nov 2020 23:59'	System	03 Aug 2020 18:20:39

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[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 (452b337832441145)', Time: '2020-11-27T10:55:15', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '2d587241-f623-4f0e-8010-fe5aa3f4a77a'	System	27 Nov 2020 16:55:24
User entered 'No (N)'	System	27 Nov 2020 16:55:24

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

Have you been exposed to someone with 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 (452b337832441145)', Time: '2020-11-27T10:55:19', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '2d587241-f623-4f0e-8010-fe5aa3f4a77a'	System	27 Nov 2020 16:55:24
User entered 'No (N)'	System	27 Nov 2020 16:55:24

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-11-27T10:55:22', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '2d587241-f623-4f0e-8010-fe5aa3f4a77a' User entered '27 Nov 2020 10:55:22'	System	27 Nov 2020 16:55:24
	System	27 Nov 2020 16:55:24

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[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 (452b337832441145)', Time: '2020-12-03T05:45:50', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '8ef4583c-7459-43f2-88ef-1d79a1138f92'	System	03 Dec 2020 11:46:19
User entered 'No (N)'	System	03 Dec 2020 11:46:19

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Have you been exposed to someone with 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 (452b337832441145)', Time: '2020-12-03T05:46:13', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '8ef4583c-7459-43f2-88ef-1d79a1138f92'	System	03 Dec 2020 11:46:19
User entered 'No (N)'	System	03 Dec 2020 11:46:19

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-12-03T05:46:17', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '8ef4583c-7459-43f2-88ef-1d79a1138f92'	System	03 Dec 2020 11:46:19
User entered '03 Dec 2020 05:46:17'	System	03 Dec 2020 11:46:19

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[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 (452b337832441145)', Time: '2020-12-09T07:17:32', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '6b5acf92-8258-4fa9-a444-015287075717'	System	09 Dec 2020 13:17:49
User entered 'No (N)'	System	09 Dec 2020 13:17:49

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

Have you been exposed to someone with 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 (452b337832441145)', Time: '2020-12-09T07:17:43', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '6b5acf92-8258-4fa9-a444-015287075717'	System	09 Dec 2020 13:17:49
User entered 'No (N)'	System	09 Dec 2020 13:17:49

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-12-09T07:17:48', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '6b5acf92-8258-4fa9-a444-015287075717'	System	09 Dec 2020 13:17:49
User entered '09 Dec 2020 07:17:48'	System	09 Dec 2020 13:17:49

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[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 (452b337832441145)', Time: '2020-12-16T07:31:17', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '1b40a60d-81f0-4506-a427-0dea7ff15ace'	System	16 Dec 2020 13:31:29
User entered 'No (N)'	System	16 Dec 2020 13:31:29

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

Have you been exposed to someone with 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 (452b337832441145)', Time: '2020-12-16T07:31:22', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '1b40a60d-81f0-4506-a427-0dea7ff15ace'	System	16 Dec 2020 13:31:29
User entered 'No (N)'	System	16 Dec 2020 13:31:29

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-12-16T07:31:26', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '1b40a60d-81f0-4506-a427-0dea7ff15ace'	System	16 Dec 2020 13:31:29
User entered '16 Dec 2020 07:31:26'	System	16 Dec 2020 13:31:29

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[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 (452b337832441145)', Time: '2020-12-25T15:30:28', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '960b8655-dcbd-4a7d-a643-200e91333fdd'	System	25 Dec 2020 21:31:02
User entered 'No (N)'	System	25 Dec 2020 21:31:02

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

Have you been exposed to someone with 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 (452b337832441145)', Time: '2020-12-25T15:30:53', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '960b8655-dcbd-4a7d-a643-200e91333fdd'	System	25 Dec 2020 21:31:02
User entered 'No (N)'	System	25 Dec 2020 21:31:02

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-12-25T15:30:56', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '960b8655-dcbd-4a7d-a643-200e91333fdd'	System	25 Dec 2020 21:31:02
User entered '25 Dec 2020 15:30:56'	System	25 Dec 2020 21:31:02

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[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 (452b337832441145)', Time: '2020-12-30T07:08:01', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '1c72bfc9-57c0-418f-a3ed-37d7915a226b'	System	30 Dec 2020 13:08:13
User entered 'No (N)'	System	30 Dec 2020 13:08:13

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

Have you been exposed to someone with 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 (452b337832441145)', Time: '2020-12-30T07:08:06', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '1c72bfc9-57c0-418f-a3ed-37d7915a226b'	System	30 Dec 2020 13:08:13
User entered 'No (N)'	System	30 Dec 2020 13:08:13

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2020-12-30T07:08:09', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '1c72bfc9-57c0-418f-a3ed-37d7915a226b' User entered '30 Dec 2020 07:08:09'	System	30 Dec 2020 13:08:13
	System	30 Dec 2020 13:08:13

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[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 (452b337832441145)', Time: '2021-01-13T06:12:29', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'bd782d52-7489-4614-a0bc-9dc64137bc5e'	System	13 Jan 2021 12:13:39
User entered 'Yes (Y)'	System	13 Jan 2021 12:13:39

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Have you been exposed to someone with 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 (452b337832441145)', Time: '2021-01-13T06:12:44', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'bd782d52-7489-4614-a0bc-9dc64137bc5e'	System	13 Jan 2021 12:13:39
User entered 'No (N)'	System	13 Jan 2021 12:13:39

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[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 (452b337832441145)', Time: '2021-01-13T06:12:52', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'bd782d52-7489-4614-a0bc-9dc64137bc5e'	System	13 Jan 2021 12:13:39
User entered 'No (N)'	System	13 Jan 2021 12:13:39

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[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 (452b337832441145)', Time: '2021-01-13T06:13:06', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'bd782d52-7489-4614-a0bc-9dc64137bc5e'	System	13 Jan 2021 12:13:39
User entered 'Yes (Y)'	System	13 Jan 2021 12:13:39

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2021-01-13T06:13:22', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'bd782d52-7489-4614-a0bc-9dc64137bc5e'	System	13 Jan 2021 12:13:39
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Jan 2021 12:13:39

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2021-01-13T06:13:29', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'bd782d52-7489-4614-a0bc-9dc64137bc5e'	System	13 Jan 2021 12:13:39
User entered '13 Jan 2021 06:13:29'	System	13 Jan 2021 12:13:39

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[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 (452b337832441145)', Time: '2021-01-22T16:39:33', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '4cf503e8-cc01-45ba-806e-fc4d3c859c74'	System	22 Jan 2021 22:39:48
User entered 'No (N)'	System	22 Jan 2021 22:39:48

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

Have you been exposed to someone with 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 (452b337832441145)', Time: '2021-01-22T16:39:37', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '4cf503e8-cc01-45ba-806e-fc4d3c859c74'	System	22 Jan 2021 22:39:48
User entered 'No (N)'	System	22 Jan 2021 22:39:48

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2021-01-22T16:39:43', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '4cf503e8-cc01-45ba-806e-fc4d3c859c74'	System	22 Jan 2021 22:39:48
User entered '22 Jan 2021 16:39:43'	System	22 Jan 2021 22:39:48

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[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 (452b337832441145)', Time: '2021-01-30T21:23:56', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'e5b7266b-e513-45de-a50d-c0fc0700579e'	System	31 Jan 2021 03:35:42
User entered 'No (N)'	System	31 Jan 2021 03:35:42

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

Have you been exposed to someone with 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 (452b337832441145)', Time: '2021-01-30T21:24:04', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'e5b7266b-e513-45de-a50d-c0fc0700579e'	System	31 Jan 2021 03:35:42
User entered 'No (N)'	System	31 Jan 2021 03:35:42

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2021-01-30T21:24:10', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'e5b7266b-e513-45de-a50d-c0fc0700579e'	System	31 Jan 2021 03:35:42
User entered '30 Jan 2021 21:24:10'	System	31 Jan 2021 03:35:42

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[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 (452b337832441145)', Time: '2021-02-04T06:25:22', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '2cba5d91-fedf-4d63-a540-f9a883920360'	System	04 Feb 2021 12:25:36
User entered 'No (N)'	System	04 Feb 2021 12:25:36

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

Have you been exposed to someone with 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 (452b337832441145)', Time: '2021-02-04T06:25:27', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '2cba5d91-fedf-4d63-a540-f9a883920360'	System	04 Feb 2021 12:25:36
User entered 'No (N)'	System	04 Feb 2021 12:25:36

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2021-02-04T06:25:31', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '2cba5d91-fedf-4d63-a540-f9a883920360'	System	04 Feb 2021 12:25:36
User entered '04 Feb 2021 06:25:31'	System	04 Feb 2021 12:25:36

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[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 (452b337832441145)', Time: '2021-02-11T19:50:14', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'd7678a5a-8acd-415e-a5a6-325c0a11796e'	System	12 Feb 2021 01:50:26
User entered 'No (N)'	System	12 Feb 2021 01:50:26

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

Have you been exposed to someone with 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 (452b337832441145)', Time: '2021-02-11T19:50:19', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'd7678a5a-8acd-415e-a5a6-325c0a11796e'	System	12 Feb 2021 01:50:26
User entered 'No (N)'	System	12 Feb 2021 01:50:26

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2021-02-11T19:50:23', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'd7678a5a-8acd-415e-a5a6-325c0a11796e'	System	12 Feb 2021 01:50:26
User entered '11 Feb 2021 19:50:23'	System	12 Feb 2021 01:50:26

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[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 (452b337832441145)', Time: '2021-02-19T09:52:39', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'd5ee9fe3-43fa-46d1-b558-11fec8c94110'	System	19 Feb 2021 15:52:52
User entered 'No (N)'	System	19 Feb 2021 15:52:52

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

Have you been exposed to someone with 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 (452b337832441145)', Time: '2021-02-19T09:52:44', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'd5ee9fe3-43fa-46d1-b558-11fec8c94110'	System	19 Feb 2021 15:52:52
User entered 'No (N)'	System	19 Feb 2021 15:52:52

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2021-02-19T09:52:48', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'd5ee9fe3-43fa-46d1-b558-11fec8c94110'	System	19 Feb 2021 15:52:52
User entered '19 Feb 2021 09:52:48'	System	19 Feb 2021 15:52:52

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[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 (452b337832441145)', Time: '2021-02-24T11:08:22-06:00', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'f11a038f-b6bc-40ec-bee9-1ef9cf5b270c' User entered 'No (N)'	System	24 Feb 2021 17:18:08

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

Have you been exposed to someone with 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 (452b337832441145)', Time: '2021-02-24T11:08:26-06:00', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'f11a038f-b6bc-40ec-bee9-1ef9cf5b270c' User entered 'No (N)'	System	24 Feb 2021 17:18:08

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2021-02-24T11:08:33-06:00', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'f11a038f-b6bc-40ec-bee9-1ef9cf5b270c' User entered '24 Feb 2021 11:08:33'	System	24 Feb 2021 17:18:08
	System	24 Feb 2021 17:18:08

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[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 (452b337832441145)', Time: '2021-03-03T09:15:45-06:00', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '86b84485-b463-4beb-8906-9122679252f0'	System	03 Mar 2021 15:15:58
User entered 'No (N)'	System	03 Mar 2021 15:15:58

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Have you been exposed to someone with 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 (452b337832441145)', Time: '2021-03-03T09:15:49-06:00', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '86b84485-b463-4beb-8906-9122679252f0'	System	03 Mar 2021 15:15:58
User entered 'No (N)'	System	03 Mar 2021 15:15:58

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2021-03-03T09:15:54-06:00', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '86b84485-b463-4beb-8906-9122679252f0'	System	03 Mar 2021 15:15:58
User entered '03 Mar 2021 09:15:54'	System	03 Mar 2021 15:15:58

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[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 (452b337832441145)', Time: '2021-03-10T18:38:01-05:00', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '5e352cac-0576-4555-9f8a-12260f1c7b2e' User entered 'No (N)'	System	10 Mar 2021 23:38:35

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

Have you been exposed to someone with 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 (452b337832441145)', Time: '2021-03-10T18:38:23-05:00', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '5e352cac-0576-4555-9f8a-12260f1c7b2e'	System	10 Mar 2021 23:38:35
User entered 'No (N)'	System	10 Mar 2021 23:38:35

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2021-03-10T18:38:27-05:00', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '5e352cac-0576-4555-9f8a-12260f1c7b2e' User entered '10 Mar 2021 18:38:27'	System	10 Mar 2021 23:38:35
	System	10 Mar 2021 23:38:35

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[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 (452b337832441145)', Time: '2021-03-17T06:37:29-05:00', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '70797ee4-1573-48d1-98ea-6961cf8560a7'	System	17 Mar 2021 11:38:00
User entered 'No (N)'	System	17 Mar 2021 11:38:00

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

Have you been exposed to someone with 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 (452b337832441145)', Time: '2021-03-17T06:37:47-05:00', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '70797ee4-1573-48d1-98ea-6961cf8560a7'	System	17 Mar 2021 11:38:00
User entered 'No (N)'	System	17 Mar 2021 11:38:00

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2021-03-17T06:37:55-05:00', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '70797ee4-1573-48d1-98ea-6961cf8560a7' User entered '17 Mar 2021 06:37:55'	System	17 Mar 2021 11:38:00
	System	17 Mar 2021 11:38:00

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[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 (452b337832441145)', Time: '2021-04-08T18:39:01-05:00', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '7048bdca-cec1-49df-b212-3076a7029b74' User entered 'No (N)'	System	08 Apr 2021 23:39:19
	System	08 Apr 2021 23:39:19

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

Have you been exposed to someone with 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 (452b337832441145)', Time: '2021-04-08T18:39:09-05:00', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '7048bdca-cec1-49df-b212-3076a7029b74'	System	08 Apr 2021 23:39:19
User entered 'No (N)'	System	08 Apr 2021 23:39:19

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2021-04-08T18:39:15-05:00', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '7048bdca-cec1-49df-b212-3076a7029b74'	System	08 Apr 2021 23:39:19
User entered '08 Apr 2021 18:39:15'	System	08 Apr 2021 23:39:19

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[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 (452b337832441145)', Time: '2021-04-16T10:34:31-05:00', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '85b5ae91-9023-433e-8add-335b2aecf5b1' User entered 'No (N)'	System	16 Apr 2021 15:34:43
	System	16 Apr 2021 15:34:43

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

Have you been exposed to someone with 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 (452b337832441145)', Time: '2021-04-16T10:34:35-05:00', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '85b5ae91-9023-433e-8add-335b2aecf5b1'	System	16 Apr 2021 15:34:43
User entered 'No (N)'	System	16 Apr 2021 15:34:43

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2021-04-16T10:34:38-05:00', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '85b5ae91-9023-433e-8add-335b2aecf5b1' User entered '16 Apr 2021 10:34:38'	System	16 Apr 2021 15:34:43
	System	16 Apr 2021 15:34:43

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[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 (452b337832441145)', Time: '2021-04-23T09:53:38-05:00', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'a233aa1c-a277-4555-9c48-0031cdb5483' User entered 'No (N)'	System	23 Apr 2021 14:54:03
	System	23 Apr 2021 14:54:03

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

Have you been exposed to someone with 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 (452b337832441145)', Time: '2021-04-23T09:53:55-05:00', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'a233aa1c-a277-4555-9c48-0031cdbc5483'	System	23 Apr 2021 14:54:03
User entered 'No (N)'	System	23 Apr 2021 14:54:03

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2021-04-23T09:53:58-05:00', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'a233aa1c-a277-4555-9c48-0031cdb5483'	System	23 Apr 2021 14:54:03
User entered '23 Apr 2021 09:53:58'	System	23 Apr 2021 14:54:03

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[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 (452b337832441145)', Time: '2021-04-30T09:14:12-05:00', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '3862941b-1e68-4f22-bfd8-a5148ce3a9e3' User entered 'No (N)'	System	30 Apr 2021 14:14:24
	System	30 Apr 2021 14:14:24

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

Have you been exposed to someone with 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 (452b337832441145)', Time: '2021-04-30T09:14:17-05:00', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '3862941b-1e68-4f22-bfd8-a5148ce3a9e3'	System	30 Apr 2021 14:14:24
User entered 'No (N)'	System	30 Apr 2021 14:14:24

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2021-04-30T09:14:21-05:00', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: '3862941b-1e68-4f22-bfd8-a5148ce3a9e3' User entered '30 Apr 2021 09:14:21'	System	30 Apr 2021 14:14:24
	System	30 Apr 2021 14:14:24

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 11:50:32

**US3062048**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 14:56:40**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:50:32
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 11:50:32

US3062048

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:56:40

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 22:47:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2021-03-01T11:57:58-06:00', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'e1bbb32f-afd9-4299-8dc0-e8beb0a81804'	System	01 Mar 2021 17:58:08
User entered 'No (N)'	System	01 Mar 2021 17:58:08

**US3062048**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 22:47:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (452b337832441145)', Time: '2021-03-01T11:58:05-06:00', User OID: 'PatientReportedOutcome (US3062048)', ODM File OID: 'e1bbb32f-afd9-4299-8dc0-e8beb0a81804' User entered '01 Mar 2021 11:58:05'	System	01 Mar 2021 17:58:08
	System	01 Mar 2021 17:58:08

**US3062048**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 22:08:47
	(b) (4)	
User entered 'Yes (Y)'	Justin Phillips (b) (4)	26 Oct 2020 20:29:22
	(b) (4)	

**US3062048**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 22:08:47
	(b) (4)	
User entered '26 Oct 2020'	Justin Phillips (b) (4)	26 Oct 2020 20:29:22
	(b) (4)	

US3062048

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:40

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 22:08:47
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Justin Phillips (b) (4)	26 Oct 2020 20:29:22
	(b) (4)	

**US3062048**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 22:08:47
User entered empty.	(b) (4)	26 Oct 2020 20:29:22
	Justin Phillips (b) (4)	
	(b) (4)	

US3062048

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User signature succeeded.	Richard Glover (b) (4)	15 Mar 2021 22:08:47
	(b) (4)	
User entered 'Yes (Y)'	Justin Phillips (b) (4)	26 Oct 2020 20:29:34
	(b) (4)	

**US3062048**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 00:48:24
User entered 'I'	System	26 Oct 2020 20:29:34

**US3062048**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered 'Yes (Y)'	Riley King (b) (4)	27 Nov 2020 16:55:06

**US3062048**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered '27 Nov 2020'	Riley King (b) (4)	27 Nov 2020 16:55:06

**US3062048**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Riley King (b) (4) (b) (4)	27 Nov 2020 16:55:06

**US3062048**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
User entered empty.	Riley King (b) (4)	27 Nov 2020 16:55:06
	(b) (4)	

**US3062048**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered 'Yes (Y)'	(b) (4) Riley King (b) (4) (b) (4)	27 Nov 2020 16:55:10

**US3062048**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User entered 'I'	System	27 Nov 2020 16:55:10

**US3062048**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered 'Yes (Y)'	(b) (4) Riley King (b) (4) (b) (4)	28 Dec 2020 16:26:54

**US3062048**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered '28 Dec 2020'	Riley King (b) (4)	28 Dec 2020 16:26:54

**US3062048**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Riley King (b) (4) (b) (4)	28 Dec 2020 16:26:54

**US3062048**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered empty.	(b) (4) Riley King (b) (4)	28 Dec 2020 16:26:54

**US3062048**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered 'Yes (Y)'	Riley King (b) (4)	28 Dec 2020 16:26:59

**US3062048**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User entered 'I'	System	28 Dec 2020 16:26:59

**US3062048**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered 'Yes (Y)'	Riley King (b) (4)	02 Feb 2021 14:45:18

**US3062048**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered '26 Jan 2021'	Riley King (b) (4)	02 Feb 2021 14:45:18

**US3062048**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Riley King (b) (4) (b) (4)	02 Feb 2021 14:45:18

**US3062048**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered empty.	(b) (4) Riley King (b) (4)	02 Feb 2021 14:45:18

**US3062048**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:40**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered 'Yes (Y)'	Riley King (b) (4)	02 Feb 2021 14:45:06

**US3062048**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User entered 'I'	System	02 Feb 2021 14:45:06

**US3062048**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:40**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered 'Yes (Y)'	Colton King (b) (4)	22 Feb 2021 19:45:40

US3062048

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:56:40

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 22FEB2021 is reported under Visit 4 Month 7 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 4 Day 209 Visit on Immunogenicity Assessment page.' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 22FEB2021 is reported under Visit 4 Month 7 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 4 Day 209 Visit on Immunogenicity Assessment page.' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6) marissa Mueller (b) (4) (b) (4)	12 Mar 2021 05:36:59 11 Mar 2021 16:47:12
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 22FEB2021 is reported under Visit 4 Month 7 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 4 Day 209 Visit on Immunogenicity Assessment page.' (Site from DM). User entered '22 Feb 2021'	(b) (4), (b) (6) Colton King (b) (4) (b) (4)	09 Mar 2021 11:17:27 22 Feb 2021 19:45:40

**US3062048**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:40**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered 'Clinic (Clinic)'	Colton King (b) (4)	22 Feb 2021 19:45:40

**US3062048**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:40**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User entered 'VISIT4'	System	22 Feb 2021 19:45:40

US3062048

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:40

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 19:21:54
	(b) (4)	

US3062048

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:40

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered '22 Feb 2021'	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 19:21:54
	(b) (4)	

**US3062048**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered '08:05'	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 19:21:54
	(b) (4)	

**US3062048**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User entered '22 Feb 2021 08:05'	System	01 Apr 2021 19:21:54

US3062048

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:40

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered '97.9' F	marissa Mueller (b) (4)	01 Apr 2021 19:21:54

**US3062048**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered 'Oral (Oral)'	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 19:21:54
	(b) (4)	

**US3062048**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered empty.	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 19:21:54
	(b) (4)	

**US3062048**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered '68'	(b) (4) marissa Mueller (b) (4) (b) (4)	01 Apr 2021 19:21:54

**US3062048**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User entered 'bpm'	System	01 Apr 2021 19:21:54

US3062048

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:40

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered '16'	(b) (4) marissa Mueller (b) (4) (b) (4)	01 Apr 2021 19:21:54

**US3062048**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User entered 'breaths/min'	System	01 Apr 2021 19:21:54

US3062048

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:40

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered '116'	(b) (4) marissa Mueller (b) (4) (b) (4)	01 Apr 2021 19:21:54

**US3062048**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User entered 'mmHg'	System	01 Apr 2021 19:21:54

US3062048

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:56:40

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered '75'	(b) (4) marissa Mueller (b) (4)	01 Apr 2021 19:21:54
	(b) (4)	

**US3062048**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User entered 'mmHg'	System	01 Apr 2021 19:21:54

**US3062048**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22

**US3062048**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 14:56:40**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22

US3062048

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:56:40

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
User entered 'No (N)'	Colton King (b) (4)	22 Feb 2021 19:45:44
	(b) (4)	

**US3062048**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 14:56:40**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered empty.	Colton King (b) (4)	22 Feb 2021 19:45:44

US3062048

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	11 Mar 2021 16:47:04
	(b) (4)	

US3062048

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:40

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered '22 Feb 2021'	(b) (4) marissa Mueller (b) (4)	11 Mar 2021 16:47:04
	(b) (4)	

**US3062048**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:56:40**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered '08:22'	marissa Mueller (b) (4)	11 Mar 2021 16:47:04

**US3062048**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:56:40**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User entered '22 Feb 2021 08:22'	System	11 Mar 2021 16:47:04

US3062048

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered 'Yes (Y)'	Colton King (b) (4)	22 Feb 2021 19:46:06

**US3062048**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 06:06:22
User entered 'I'	System	22 Feb 2021 19:46:06

**US3062048**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:41:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	31 Mar 2021 19:50:38
	(b) (4)	

**US3062048**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:41:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered '29 Mar 2021'	marissa Mueller (b) (4)	31 Mar 2021 19:50:38

**US3062048**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 14:56:40**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:41:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) marissa Mueller (b) (4)	31 Mar 2021 19:50:38
	(b) (4)	

US3062048

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:56:40

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:41:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered empty.	(b) (4) marissa Mueller (b) (4)	31 Mar 2021 19:50:38
	(b) (4)	

US3062048

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:56:40

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:41:11
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered 'Yes (Y)'	(b) (4) marissa Mueller (b) (4)	31 Mar 2021 19:50:48
	(b) (4)	

**US3062048**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 14:56:40**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:41:11
User entered 'I'	System	31 Mar 2021 19:50:48

**US3062048**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:40**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4) (b) (4)	26 Jan 2021 21:21:58

**US3062048**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:40**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
User entered '26 Jan 2021'	Colton King (b) (4)	26 Jan 2021 21:21:58
	(b) (4)	

**US3062048**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:40**

[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 21:08:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered 'Clinic (Clinic)'	(b) (4) Colton King (b) (4) (b) (4)	26 Jan 2021 21:21:58

**US3062048**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 14:56:40**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:29
User entered 'UNBLND_DECIDE'	System	26 Jan 2021 21:21:58

US3062048

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:56:40

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
User entered '26 Jan 2021'	Colton King (b) (4)	26 Jan 2021 21:22:19
	(b) (4)	

**US3062048**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:56:40**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:13:36

**US3062048**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:56:40**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	26 Jan 2021 21:22:19
	(b) (4)	

US3062048

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:56:40

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	(b) (4) marissa Mueller (b) (4)	31 Mar 2021 16:10:45
User entered empty. WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 02:13:36

**US3062048**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:56:40**

**Date of unblinding** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
User entered '26 Jan 2021'	Colton King (b) (4)	26 Jan 2021 21:22:19
	(b) (4)	

US3062048

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:56:40

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Colton King (b) (4)	26 Jan 2021 21:22:19
	(b) (4)	

**US3062048**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:56:40**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Colton King (b) (4)	26 Jan 2021 21:22:19

**US3062048**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:56:40**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Colton King (b) (4)	26 Jan 2021 21:22:19
	(b) (4)	

US3062048

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 14:56:40

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
User entered 'No (N)'	Colton King (b) (4)	26 Jan 2021 21:22:19
	(b) (4)	

**US3062048**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:56:40**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:29
User entered empty.	System	26 Jan 2021 21:22:19

**US3062048**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 14:56:40**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:29
User entered empty.	System	26 Jan 2021 21:22:19

US3062048

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:40

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
User entered 'Yes (Y)'	Colton King (b) (4)	26 Jan 2021 21:22:38
	(b) (4)	

US3062048

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:56:40

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
User entered '26 Jan 2021'	Colton King (b) (4)	26 Jan 2021 21:22:38
	(b) (4)	

**US3062048**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:56:40**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
User entered '14:09'	Colton King (b) (4)	26 Jan 2021 21:22:38
	(b) (4)	

**US3062048**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 14:56:40**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:29
User entered '26 Jan 2021 14:09'	System	26 Jan 2021 21:22:38

**US3062048**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 14:56:40**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered 'Yes (Y)'	(b) (4) Colton King (b) (4) (b) (4)	26 Jan 2021 21:22:51

**US3062048**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 14:56:40**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
User entered '26 Jan 2021'	Colton King (b) (4)	26 Jan 2021 21:22:51
	(b) (4)	

**US3062048**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 14:56:40**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
User entered '14:06'	Colton King (b) (4)	26 Jan 2021 21:22:51
	(b) (4)	

**US3062048**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 14:56:40**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:08:29
User entered '26 Jan 2021 14:06'	System	26 Jan 2021 21:22:51

US3062048

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:56:40

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:34
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
User closed query 'please verify headache 11Nov per hosp record' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 17:48:59
Query 'please verify headache 11Nov per hosp record' answered with 'Added' (Site from CRA).	Riley King (b) (4)	16 Mar 2021 19:02:01
	(b) (4)	
User opened query 'please verify headache 11Nov per hosp record' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 20:45:53
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:17:13
	(b) (4)	
User entered 'Yes (Y)' reason for change: New Information	Cayla Lawless (b) (4)	14 Jan 2021 21:17:16
	(b) (4)	
User entered 'No (N)'	marissa Mueller (b) (4)	01 Sep 2020 19:45:33
	(b) (4)	

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:40**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:03
User entered	System	15 Jan 2021 13:34:47
'USA-US090-2021-mRNA-1273-P301000002'		
User entered 'New'	(b) (4), (b) (6)	15 Jan 2021 13:34:47

US3062048

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:40

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Lumbar spinal cord and nerve root disorders, PT: Lumbar radiculopathy, LLT: Lumbar radiculopathy - version MedDRA\23.0.	Coder Import (b) (4)	22 Jan 2021 18:43:03
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	22 Jan 2021 18:43:03
	(b) (4)	
User closed query 'PV Query: Please clarify if this needs to be considered as event since the patient had worsening of back pain prior to study start as per source documents.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 17:07:28
User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 17:07:21
Data point term sent to Coder	System	20 Jan 2021 18:08:00
Query 'PV Query: Please clarify if this needs to be considered as event since the patient had worsening of back pain prior to study start as per source documents.' answered with 'SAE term changed. ' (Site from Safety).	Riley King (b) (4)	20 Jan 2021 18:07:52
	(b) (4)	
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' answered with 'Changed from low back pain to Lumbar radiculopathy involving the left S1 nerve root.' (Site from Safety).	Riley King (b) (4)	20 Jan 2021 18:07:44
	(b) (4)	
Coding entries removed.	Riley King (b) (4)	20 Jan 2021 18:07:25
	(b) (4)	
User entered 'Lumbar radiculopathy involving the left S1 nerve root' reason for change: New Information	Riley King (b) (4)	20 Jan 2021 18:07:25
	(b) (4)	
User opened query 'PV Query: Please clarify if this needs to be considered as event since the patient had worsening of back pain prior to study start as per source documents.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 15:04:18
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 15:03:19

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:40

[Adverse event](#)

Audit	User		Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\\23.0.	Coder Import	(b) (4)	14 Jan 2021 21:21:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import	(b) (4)	14 Jan 2021 21:21:57
Data point term sent to Coder	System		14 Jan 2021 21:21:14
User entered 'low back pain'	Cayla Lawless	(b) (4)	14 Jan 2021 21:20:32
	(b) (4)		

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'Yes (Y)'	Cayla Lawless (b) (4)	14 Jan 2021 21:20:32
	(b) (4)	

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'No (N)'	Cayla Lawless (b) (4)	14 Jan 2021 21:20:32
	(b) (4)	

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'No (N)'	Cayla Lawless (b) (4)	14 Jan 2021 21:20:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
	(b) (4), (b) (6)	
User closed query 'PV Query: Please clarify the event start date.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 17:07:32
Query 'PV Query: Please clarify the event start date.' answered with 'Start date is correct. ' (Site from Safety).	Riley King (b) (4)	20 Jan 2021 18:08:03
	(b) (4)	
User opened query 'PV Query: Please clarify the event start date.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 15:04:01
User entered '11 Jan 2021'	Cayla Lawless (b) (4)	14 Jan 2021 21:20:32
	(b) (4)	

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Cayla Lawless (b) (4)	14 Jan 2021 21:20:32
	(b) (4)	

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:40**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Jan 2021 21:20:32

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'No (N)'	Cayla Lawless (b) (4)	14 Jan 2021 21:20:32
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:40**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '12 Jan 2021'	Cayla Lawless (b) (4)	14 Jan 2021 21:20:32
	(b) (4)	

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:40**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Cayla Lawless (b) (4)	14 Jan 2021 21:20:32
	(b) (4)	

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:40**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Jan 2021 21:20:32

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'Grade 4 (Grade 4)'	Cayla Lawless (b) (4)	14 Jan 2021 21:20:32
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'Yes (Y)'	Cayla Lawless (b) (4)	14 Jan 2021 21:20:32
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '0'	Cayla Lawless (b) (4)	14 Jan 2021 21:20:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:40

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '0'	Cayla Lawless (b) (4)	14 Jan 2021 21:20:32
	(b) (4)	

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'I'	Cayla Lawless (b) (4)	14 Jan 2021 21:20:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:40

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '11 Jan 2021'	Cayla Lawless (b) (4)	14 Jan 2021 21:20:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:40

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
	(b) (4), (b) (6)	21 Jan 2021 17:08:00
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).		
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'No discharge summary available.' (Site from Safety).	Riley King (b) (4)	20 Jan 2021 18:08:21
	(b) (4)	
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 15:03:01
User entered '12 Jan 2021'	Cayla Lawless (b) (4)	14 Jan 2021 21:20:32
	(b) (4)	

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'No (N)'	Cayla Lawless (b) (4)	14 Jan 2021 21:20:32
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Cayla Lawless (b) (4)	14 Jan 2021 21:20:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '0'	Cayla Lawless (b) (4)	14 Jan 2021 21:20:32
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '0'	Cayla Lawless (b) (4)	14 Jan 2021 21:20:32
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '0'	Cayla Lawless (b) (4)	14 Jan 2021 21:20:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:40

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'Not Related (NOT RELATED)'	Cayla Lawless (b) (4)	14 Jan 2021 21:20:32
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'Not Related (NOT RELATED)'	Cayla Lawless (b) (4)	14 Jan 2021 21:20:32
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'Not Applicable (NOT APPLICABLE)'	Cayla Lawless (b) (4)	14 Jan 2021 21:20:32
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:40**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '0'	Cayla Lawless (b) (4)	14 Jan 2021 21:20:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
	(b) (4), (b) (6)	21 Jan 2021 17:08:04
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Conmed and Con procedure updated.' (Site from Safety).	Riley King (b) (4)	20 Jan 2021 18:08:45
	(b) (4)	
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 15:03:45
User entered 'I'	Cayla Lawless (b) (4)	14 Jan 2021 21:20:32
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'I'	Cayla Lawless (b) (4)	14 Jan 2021 21:20:32
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Cayla Lawless (b) (4)	14 Jan 2021 21:20:32
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 14:56:40**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Cayla Lawless (b) (4)	14 Jan 2021 21:20:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:56:40

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: SAE Narrative = WAS RECEIVING CONSERVATIVE TREATMENT (PHYSICAL THERAPY). However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 13:08:05
User closed query 'Per DM CLR: Narrative = PRE OP MRI AND X-RAY PERFORMED. However, these were not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 15:04:04
Query 'Per DM CLR: SAE Narrative = WAS RECEIVING CONSERVATIVE TREATMENT (PHYSICAL THERAPY). However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' answered with 'Added to con procedures. ' (Site from DM).	Riley King (b) (4) (b) (4)	26 Feb 2021 14:51:55
User closed query 'Per DM CLR: Narrative = SURGERY PERFORMED WAS A LEFT HEMI LAMINOTOMY DECOMPRESSION WITH PARTIAL MEDIAL FACETECTOMY AND EXCISION OF L5-S1 FACET SYNOVIAL CYST. However, these were not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 14:48:37

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative = SURGERY PERFORMED WAS A LEFT HEMI LAMINOTOMY DECOMPRESSION WITH PARTIAL MEDIAL FACETECTOMY AND EXCISION OF L5-S1 FACET SYNOVIAL CYST. However, these were not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Both of these procedures are recorded and entered into EDC. ' (Site from DM).	Riley King (b) (4) (b) (4)	24 Feb 2021 16:59:41
Query 'Per DM CLR: Narrative = PRE OP MRI AND X-RAY PERFORMED. However, these were not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'reconciled ' (Site from DM).	Riley King (b) (4) (b) (4)	24 Feb 2021 16:55:24
User closed query 'PV Query: Please consider whether the patient's low back pain should be added to Medical History.' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 16:51:43
User opened query 'Per DM CLR: Narrative = SURGERY PERFORMED WAS A LEFT HEMI LAMINOTOMY DECOMPRESSION WITH PARTIAL MEDIAL FACETECTOMY AND EXCISION OF L5-S1 FACET SYNOVIAL CYST. However, these were not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		15 Feb 2021 01:50:05
User opened query 'Per DM CLR: Narrative = PRE OP MRI AND X-RAY PERFORMED. However, these were not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		15 Feb 2021 01:49:46
Query 'PV Query: Please consider whether the patient's low back pain should be added to Medical History.' answered with 'updated' (Site from Safety).	marissa Mueller (b) (4) (b) (4)	12 Feb 2021 17:43:47
User opened query 'PV Query: Please consider whether the patient's low back pain should be added to Medical History.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 17:45:33

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = WAS RECEIVING CONSERVATIVE TREATMENT (PHYSICAL THERAPY). However, please review and verify if this should be recorded as part of the subject's Medical History. If yes, ensure to record this medical condition in the MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Jan 2021 06:31:49
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Jan 2021 17:08:08
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'Per records no COVID-19 testing done during hospital admission. ' (Site from Safety).	Riley King (b) (4) (b) (4)	20 Jan 2021 18:11:09

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'AT SCREENING VISIT, SUBJECT REPORTED LOW BACK PAIN BEGINNING IN 1964. ON 1/14/21, SUBJECT REPORTED THAT HIS LOW BACK PAIN BEGAN WORSENING PRIOR TO STUDY START AND WAS RECEIVING CONSERVATIVE TREATMENT, EPIDURAL INJECTION AND PHYSICAL THERAPY. CONSERVATIVE TREATMENT WAS INEFFECTIVE, THEREFORE, SUBJECT WAS SCHEDULED FOR LAMINECTOMY. SUBJECT REPORTS LAMINECTOMY ON 11JAN2021 WITH NO ISSUES OR CONCERNS. SUBJECT REPORTS HE WAS GIVEN MEDICATION WHILE IN THE HOSPITAL, BUT UNCERTAIN OF NAMES AND DOSAGES. SUBJECT WAS THEN RELEASED FROM HOSPITAL ON 12JAN2021. RELEASE OF RECORDS MAILED TO SUBJECT. UPDATE TO BE PROVIDED UPON RECEIPT OF NEW INFORMATION. Received medical records 1/19/2021. Changed SAE term from Low back pain to Lumbar radiculopathy involving the left S1 nerve root. Prior to surgery Pre op MRI and X-ray performed. MRI and X-ray show Lumbar lateral recess stenosis at L5-S1 on the left side and Left L5-S1 lumbar facet synovial cyst. Surgery performed was a left Hemi laminotomy decompression with partial medial facetectomy and excision of L5-S1 facet synovial cyst. Source updated with medication, procedures, and AEs' reason for change: New Information	Riley King (b) (4) (b) (4)	20 Jan 2021 18:10:15
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 15:02:33

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'At screening visit, subject reported low back pain beginning in 1964. On 1/14/21, subject reported that his low back pain began worsening prior to study start and was receiving conservative treatment, epidural injection and physical therapy. Conservative treatment was ineffective, therefore, subject was scheduled for laminectomy. Subject reports laminectomy on 11JAN2021 with no issues or concerns. Subject reports he was given medication while in the hospital, but uncertain of names and dosages. Subject was then released from hospital on 12JAN2021. Release of records mailed to subject. Update to be provided upon receipt of new information.'	Cayla Lawless (b) (4) (b) (4)	14 Jan 2021 21:20:32

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Jan 2021 21:20:32

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Jan 2021 21:20:32

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Jan 2021 21:20:32

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 16:52:21

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:31:07
DataPoint Un-verified.		01 Mar 2021 20:24:31
DataPoint Verified.		01 Mar 2021 20:23:53
User closed query 'For coding purposes, please clarify/provide more information for term DUROTOMY. Is this a Durotomy a Dural tear or the Durotomy procedure. Please update the term with your response.' (Site from Coder).		14 Feb 2021 16:56:15
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Neurological and psychiatric procedural complications, PT: Dural tear, LLT: Incidental durotomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Feb 2021 17:41:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Feb 2021 17:41:48
Data point term sent to Coder	System	12 Feb 2021 17:40:32
Query 'For coding purposes, please clarify/provide more information for term DUROTOMY. Is this a Durotomy a Dural tear or the Durotomy procedure. Please update the term with your response.' answered with 'updated' (Site from Coder).	marissa Mueller (b) (4) (b) (4)	12 Feb 2021 17:40:19
Coding entries removed.	marissa Mueller (b) (4) (b) (4)	12 Feb 2021 17:40:13
User entered 'incidental DUROTOMY' reason for change: Data Entry Error	marissa Mueller (b) (4) (b) (4)	12 Feb 2021 17:40:13
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Neurological and psychiatric procedural complications, PT: Dural tear, LLT: Incidental durotomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Jan 2021 19:05:10

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EAB) (1725)

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[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	21 Jan 2021 19:05:10
User opened query 'For coding purposes, please clarify/provide more information for term DUROTOMY. Is this a Durotomy a Dural tear or the Durotomy procedure. Please update the term with your response.' (Site from Coder).	(b) (4), (b) (6)	21 Jan 2021 18:56:02
Query 'For coding purposes, DUROTOMY is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' canceled (Site from Coder).	(b) (4), (b) (6)	21 Jan 2021 18:45:03
User opened query 'For coding purposes, DUROTOMY is not codable as entered. Procedures are not captured as an Adverse Event. Please delete the term or provide the diagnosis or underlying condition that necessitated the surgery/procedure.' (Site from Coder).	(b) (4), (b) (6)	21 Jan 2021 18:39:08
Data point term sent to Coder	System	20 Jan 2021 17:45:35
User entered 'Durotomy'	Riley King (b) (4)	20 Jan 2021 17:45:22
	(b) (4)	

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:31:13
DataPoint Un-verified.		01 Mar 2021 20:28:47
DataPoint Verified.		01 Mar 2021 20:23:53
User entered 'Yes (Y)'	Riley King (b) (4)	20 Jan 2021 17:45:22

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Form: Adverse Events (2)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:31:15
DataPoint Un-verified.		01 Mar 2021 20:28:50
DataPoint Verified.		01 Mar 2021 20:23:53
User entered 'No (N)'	Riley King (b) (4) (b) (4)	20 Jan 2021 17:45:22

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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)	29 Apr 2021 09:32:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 20:31:18
DataPoint Verified.		01 Mar 2021 20:28:51
DataPoint Verified.		01 Mar 2021 20:23:53
User entered 'No (N)'	Riley King (b) (4)	20 Jan 2021 17:45:22
	(b) (4)	

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4)	01 Mar 2021 20:31:24
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 20:28:53
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '11 Jan 2021'	Riley King (b) (4)	20 Jan 2021 17:45:22
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4)	01 Mar 2021 20:31:21
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 20:28:54
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4)	20 Jan 2021 17:45:22
	(b) (4)	

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**Form: Adverse Events (2)**

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:41
User entered empty.	System	20 Jan 2021 17:45:22

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:31:26
DataPoint Un-verified.		01 Mar 2021 20:28:56
DataPoint Verified.		01 Mar 2021 20:23:53
User entered 'No (N)'	Riley King (b) (4) (b) (4)	20 Jan 2021 17:45:22

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**Form: Adverse Events (2)**

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*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:31:29
DataPoint Un-verified.		01 Mar 2021 20:28:57
DataPoint Verified.		01 Mar 2021 20:23:53
User entered '12 Jan 2021'	Riley King (b) (4) (b) (4)	20 Jan 2021 17:45:22

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End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:31:35
DataPoint Un-verified.		01 Mar 2021 20:28:58
DataPoint Verified.		01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 17:45:22

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:41
User entered empty.	System	20 Jan 2021 17:45:22

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:31:32
DataPoint Un-verified.		01 Mar 2021 20:29:03
DataPoint Verified.		01 Mar 2021 20:23:53
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4) (b) (4)	20 Jan 2021 17:45:22

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Folder: Adverse Events

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:31:40
DataPoint Un-verified.		01 Mar 2021 20:29:01
DataPoint Verified.		01 Mar 2021 20:23:53
User closed query 'Per MM: please confirm if this event does not meet serious criteria due to its medical significance' (Site from DM).		19 Feb 2021 13:19:11
Query 'Per MM: please confirm if this event does not meet serious criteria due to its medical significance' answered with 'Does not meet criteria. Did not prolong hospitalization and was not the initial reason for hospitalization.' (Site from DM).	Cayla Lawless (b) (4) (b) (4)	16 Feb 2021 18:11:25
User opened query 'Per MM: please confirm if this event does not meet serious criteria due to its medical significance' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 15:42:51
User entered 'No (N)'	Riley King (b) (4) (b) (4)	20 Jan 2021 17:45:22

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Form: Adverse Events (2)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:31:43
DataPoint Un-verified.		01 Mar 2021 20:29:05
DataPoint Verified.		01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4) (b) (4)	20 Jan 2021 17:45:22

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 20:31:45
DataPoint Verified.		01 Mar 2021 20:29:08
DataPoint Verified.		01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4)	20 Jan 2021 17:45:22
	(b) (4)	

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:31:47
DataPoint Un-verified.		01 Mar 2021 20:29:09
DataPoint Verified.		01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4) (b) (4)	20 Jan 2021 17:45:22

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:31:50
DataPoint Un-verified.		01 Mar 2021 20:29:11
DataPoint Verified.		01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 17:45:22

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:31:52
DataPoint Un-verified.		01 Mar 2021 20:29:13
DataPoint Verified.		01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 17:45:22

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**Form: Adverse Events (2)**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4)	01 Mar 2021 20:31:54
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 20:29:15
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4)	20 Jan 2021 17:45:22
	(b) (4)	

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:31:55
DataPoint Un-verified.		01 Mar 2021 20:29:17
DataPoint Verified.		01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 17:45:22

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:31:57
DataPoint Un-verified.		01 Mar 2021 20:29:18
DataPoint Verified.		01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4) (b) (4)	20 Jan 2021 17:45:22

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:31:58
DataPoint Un-verified.		01 Mar 2021 20:29:20
DataPoint Verified.		01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4) (b) (4)	20 Jan 2021 17:45:22

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:32:01
DataPoint Un-verified.		01 Mar 2021 20:29:22
DataPoint Verified.		01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4) (b) (4)	20 Jan 2021 17:45:22

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4)	01 Mar 2021 20:32:03
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 20:29:25
DataPoint Verified.	(b) (4)	01 Mar 2021 20:23:53
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 17:45:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Jan 2021 17:45:37
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Riley King (b) (4)	20 Jan 2021 17:45:37
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	20 Jan 2021 17:45:22
User entered empty.	System	20 Jan 2021 17:45:22
	Riley King (b) (4)	20 Jan 2021 17:45:22
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:32:05
DataPoint Un-verified.		01 Mar 2021 20:29:27
DataPoint Verified.		01 Mar 2021 20:23:53
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 17:45:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Jan 2021 17:45:37
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Riley King (b) (4) (b) (4)	20 Jan 2021 17:45:37
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 17:45:22
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 17:45:22

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:32:06
DataPoint Un-verified.		01 Mar 2021 20:29:29
DataPoint Verified.		01 Mar 2021 20:23:53
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 17:45:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Jan 2021 17:45:37
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Riley King (b) (4) (b) (4)	20 Jan 2021 17:45:37
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 17:45:22
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 17:45:22

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:14:19
User entered '0' reason for change: Data Entry Error		18 Mar 2021 16:32:23
DataPoint Un-verified.		01 Mar 2021 20:29:30
DataPoint Verified.		01 Mar 2021 20:23:53
User entered '1'	Riley King (b) (4) (b) (4)	20 Jan 2021 17:45:22

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Folder: Adverse Events

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
User closed query 'please check CM box from NONE' (Site from CRA). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:14:30 18 Mar 2021 17:14:22
Query 'please check CM box from NONE' answered with 'Reconciled ' (Site from CRA).	Riley King (b) (4) (b) (4)	18 Mar 2021 16:32:31
User entered '1' reason for change: Data Entry Error	Riley King (b) (4) (b) (4)	18 Mar 2021 16:32:23
User opened query 'please check CM box from NONE' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 14:33:13
User closed query 'please verify Duraseal glue as per operative note per source' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 14:33:13
Query 'please verify Duraseal glue as per operative note per source' answered with 'reconciled ' (Site from CRA).	Riley King (b) (4) (b) (4)	11 Mar 2021 16:55:00
User opened query 'please verify Duraseal glue as per operative note per source' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 20:34:08 01 Mar 2021 20:29:32
DataPoint Verified.		01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4) (b) (4)	20 Jan 2021 17:45:22

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:14:25
DataPoint Un-verified.		01 Mar 2021 20:29:35
DataPoint Verified.		01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4)	20 Jan 2021 17:45:22
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4)	01 Mar 2021 20:32:28
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 20:29:36
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4)	20 Jan 2021 17:45:22
	(b) (4)	

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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)	29 Apr 2021 09:32:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:14:36
DataPoint Un-verified.		01 Mar 2021 20:29:48
DataPoint Verified.		01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 17:45:22

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:41
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:14:33
DataPoint Un-verified.		01 Mar 2021 20:29:40
DataPoint Verified.		01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 17:45:22

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:56:40**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:41
User entered '0'	System	20 Jan 2021 17:45:22

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:56:40**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:41
User entered '1'	System	20 Jan 2021 17:45:22

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 14:56:40**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:41

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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 20:36:05
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Tendon, ligament and cartilage disorders, HLT: Ligament disorders, PT: Ligamentum flavum hypertrophy, LLT: Ligamentum flavum hypertrophy - version MedDRA\\23.0.	Coder Import (b) (4)	20 Jan 2021 17:48:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Jan 2021 17:48:07
Data point term sent to Coder	System	20 Jan 2021 17:47:37
User entered 'Ligamentum flavum hypertrophy'	Riley King (b) (4)	20 Jan 2021 17:47:25
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:56:40**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 20:36:07
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'Yes (Y)'	Riley King (b) (4)	20 Jan 2021 17:47:25
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:36:09
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'No (N)'	Riley King (b) (4) (b) (4)	20 Jan 2021 17:47:25

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**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)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 20:36:11
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'No (N)'	Riley King (b) (4)	20 Jan 2021 17:47:25
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 20:36:14
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '11 Jan 2021'	Riley King (b) (4)	20 Jan 2021 17:47:25
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:56:40**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 20:36:13
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4)	20 Jan 2021 17:47:25
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:56:40**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Jan 2021 17:47:25

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[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 20:36:18
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 17:47:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Jan 2021 17:47:35
User entered 'Yes (Y)' reason for change: Data Entry Error	Riley King (b) (4)	20 Jan 2021 17:47:35
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 17:47:25
User entered empty.	Riley King (b) (4)	20 Jan 2021 17:47:25
	(b) (4)	

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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)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:36:20
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 17:47:25

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:56:40**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 20:36:23
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4)	20 Jan 2021 17:47:25
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:56:40**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Jan 2021 17:47:25

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:36:25
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4) (b) (4)	20 Jan 2021 17:47:25

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:56:40**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 20:36:28
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'No (N)'	Riley King (b) (4)	20 Jan 2021 17:47:25
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:56:40**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Un-verified.	(b) (4)	01 Mar 2021 20:36:30
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4)	20 Jan 2021 17:47:25

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4)	20 Jan 2021 17:47:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:56:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4)	20 Jan 2021 17:47:25
	(b) (4)	

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4)	20 Jan 2021 17:47:25
	(b) (4)	

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[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4)	20 Jan 2021 17:47:25
	(b) (4)	

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**Folder: Adverse Events**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4)	20 Jan 2021 17:47:25
	(b) (4)	

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**Folder: Adverse Events**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4)	20 Jan 2021 17:47:25
	(b) (4)	

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4)	20 Jan 2021 17:47:25
	(b) (4)	

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**Folder: Adverse Events**

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4)	20 Jan 2021 17:47:25
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4)	20 Jan 2021 17:47:25
	(b) (4)	

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:56:40**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	20 Jan 2021 17:47:25
	(b) (4)	

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:56:40**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	20 Jan 2021 17:47:25
	(b) (4)	

US3062048

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:56:40

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
	(b) (4), (b) (6)	
User closed query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate.	(b) (4), (b) (6)	14 Feb 2021 21:17:07
' (Site from DM).		
Query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate.	Colton King (b) (4)	11 Feb 2021 22:28:19
	(b) (4)	
' answered with 'updated' (Site from DM).		
User entered 'Not Applicable (NOT APPLICABLE)'	Colton King (b) (4)	11 Feb 2021 22:28:12
reason for change: Data Entry Error	(b) (4)	
User opened query 'Per CDM: Per CCGs, if the AE started after the last dose, 'Not applicable' should be selected for Action taken with investigational product. Please review and update this field as appropriate.	(b) (4), (b) (6)	27 Jan 2021 06:32:07
' (Site from DM).		
User entered 'None (NONE)'	Riley King (b) (4)	20 Jan 2021 17:47:25
	(b) (4)	

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:56:40**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'I'	Riley King (b) (4)	20 Jan 2021 17:47:25
	(b) (4)	

US3062048

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:56:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4)	20 Jan 2021 17:47:25
	(b) (4)	

US3062048

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:56:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4)	20 Jan 2021 17:47:25
	(b) (4)	

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:56:40**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Riley King (b) (4)	20 Jan 2021 17:47:25
	(b) (4)	

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:56:40**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4)	20 Jan 2021 17:47:25
	(b) (4)	

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:56:40**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4)	20 Jan 2021 17:47:25
	(b) (4)	

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:56:40**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Jan 2021 17:47:25

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 14:56:40**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Jan 2021 17:47:25

US3062048

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:56:40

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc degeneration, LLT: Lumbar disc degeneration - version MedDRA\\23.0.	Coder Import (b) (4)	20 Jan 2021 17:54:11
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Jan 2021 17:54:11
	(b) (4)	
Data point term sent to Coder	System	20 Jan 2021 17:52:40
User entered 'Lumbar disc degeneration'	Riley King (b) (4)	20 Jan 2021 17:52:03
	(b) (4)	

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:56:40**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'Yes (Y)'	Riley King (b) (4)	20 Jan 2021 17:52:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:56:40

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'No (N)'	Riley King (b) (4)	20 Jan 2021 17:52:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:56:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'No (N)'	Riley King (b) (4)	20 Jan 2021 17:52:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:56:40

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '11 Jan 2021'	Riley King (b) (4)	20 Jan 2021 17:52:03
	(b) (4)	

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:56:40**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4)	20 Jan 2021 17:52:03
	(b) (4)	

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:56:40**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Jan 2021 17:52:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:56:40

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'Yes (Y)' reason for change: Per Query Resolution	Riley King (b) (4)	20 Jan 2021 19:25:22
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	20 Jan 2021 17:52:03
	(b) (4)	

US3062048

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:56:40

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	20 Jan 2021 19:25:22
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	20 Jan 2021 17:52:03
User entered empty.	Riley King (b) (4)	20 Jan 2021 17:52:03
	(b) (4)	

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:56:40**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4)	20 Jan 2021 17:52:03
	(b) (4)	

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:56:40**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Jan 2021 17:52:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:56:40

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'Grade 2/Moderate (Grade 2/Moderate)	Riley King (b) (4)	20 Jan 2021 19:25:22
reason for change: Per Query Resolution	(b) (4)	
User entered 'Grade 4 (Grade 4)'	Riley King (b) (4)	20 Jan 2021 17:52:03
	(b) (4)	

US3062048

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:56:40

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	20 Jan 2021 19:25:22
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered by data change (Site from System).	System	20 Jan 2021 19:25:22
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	20 Jan 2021 17:52:03
User entered 'No (N)'	Riley King (b) (4)	20 Jan 2021 17:52:03
	(b) (4)	

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:56:40**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4)	20 Jan 2021 17:52:03
	(b) (4)	

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:56:40**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4)	20 Jan 2021 17:52:03
	(b) (4)	

US3062048

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:56:40

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4)	20 Jan 2021 17:52:03
	(b) (4)	

US3062048

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:56:40

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4)	20 Jan 2021 17:52:03
	(b) (4)	

US3062048

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:56:40

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4)	20 Jan 2021 17:52:03
	(b) (4)	

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:56:40**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4)	20 Jan 2021 17:52:03
	(b) (4)	

US3062048

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:56:40

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4)	20 Jan 2021 17:52:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:56:40

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4)	20 Jan 2021 17:52:03
	(b) (4)	

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:56:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4)	20 Jan 2021 17:52:03
	(b) (4)	

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:56:40**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4)	20 Jan 2021 17:52:03
	(b) (4)	

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:56:40**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	20 Jan 2021 17:52:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:56:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4)	20 Jan 2021 17:52:03
	(b) (4)	

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:56:40**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4)	20 Jan 2021 17:52:03
	(b) (4)	

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:56:40**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'I'	Riley King (b) (4)	20 Jan 2021 17:52:03
	(b) (4)	

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:56:40**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4)	20 Jan 2021 17:52:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:56:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4)	20 Jan 2021 17:52:03
	(b) (4)	

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:56:40**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Riley King (b) (4)	20 Jan 2021 17:52:03
	(b) (4)	

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:56:40**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4)	20 Jan 2021 17:52:03
	(b) (4)	

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:56:40**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4)	20 Jan 2021 17:52:03
	(b) (4)	

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:56:40**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Jan 2021 17:52:03

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 09 Jun 2021 14:56:40**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Jan 2021 17:52:03

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:56:40**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:51
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	(b) (4), (b) (6)	16 Feb 2021 16:52:44

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:56:40

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:51
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Synovial and bursal disorders, HLT: Synovial disorders, PT: Spinal synovial cyst, LLT: Spinal synovial cyst - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Jan 2021 18:23:03
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Jan 2021 18:23:03
Data point term sent to Coder	System	20 Jan 2021 19:26:48
User entered 'Left L5-S1 lumbar facet synovial cyst'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:26:29

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:56:40**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:51
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'Yes (Y)'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:26:29

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:56:40**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:51
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'No (N)'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:26:29

US3062048

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:56:40

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:51
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'No (N)'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:26:29

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:51
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '11 Jan 2021'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:26:29

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:56:40**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:51
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 19:26:29

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:56:40**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:51
User entered empty.	System	20 Jan 2021 19:26:29

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:56:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:51
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'No (N)'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:26:29

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:56:40**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:51
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '12 Jan 2021'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:26:29

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:56:40**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:51
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 19:26:29

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:56:40**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:51
User entered empty.	System	20 Jan 2021 19:26:29

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:56:40**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:51
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:26:29

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:56:40**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:51
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'No (N)'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:26:29

US3062048

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:56:40

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:51
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:26:29

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:56:40**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:51
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:26:29

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:56:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:51
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4)	20 Jan 2021 19:26:29

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:56:40**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:51
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 19:26:29

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:56:40**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:51
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 19:26:29

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:56:40**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:51
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 19:26:29

US3062048

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:56:40

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:51
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4)	20 Jan 2021 19:26:29

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:56:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:51
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4)	20 Jan 2021 19:26:29

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:56:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:51
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:26:29

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:56:40**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:51
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:26:29

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:56:40**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:51
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:26:29

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:56:40**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:51
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:26:29

US3062048

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:56:40

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:51
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 19:26:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Jan 2021 19:26:38
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Riley King (b) (4) (b) (4)	20 Jan 2021 19:26:38
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 19:26:29
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 19:26:29

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:56:40**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:51
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:26:29

US3062048

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:56:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:51
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:26:29

US3062048

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:56:40

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:51
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 13:24:25
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'Concomitant procedure added per source information' (Site from DM).	Cayla Lawless (b) (4) (b) (4)	16 Feb 2021 18:09:41
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 01:50:35
User entered 'I'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:26:29

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:56:40**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:51
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:26:29

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:56:40**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:51
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 19:26:29

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:56:40**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:51
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 19:26:29

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:56:40**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:51
User entered '0'	System	20 Jan 2021 19:26:29

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:56:40**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:51
User entered '1'	System	20 Jan 2021 19:26:29

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 09 Jun 2021 14:56:40**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:51

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:56:40**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:53

US3062048

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:56:40

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:53
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Spine and neck deformities, PT: Vertebral lateral recess stenosis, LLT: Lumbosacral lateral recess stenosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Jan 2021 18:27:04
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Jan 2021 18:27:04
Data point term sent to Coder	System	20 Jan 2021 19:28:50
User entered 'Lumbar lateral recess stenosis at L5-S1 on the left side'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:27:51

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:56:40**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:53
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'Yes (Y)'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:27:51

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:56:40**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:53
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'No (N)'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:27:51

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:56:40**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:53
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'No (N)'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:27:51

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:53
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '11 Jan 2021'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:27:51

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:56:40**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:53
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 19:27:51

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:56:40**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:53
User entered empty.	System	20 Jan 2021 19:27:51

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:56:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:53
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'No (N)'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:27:51

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:56:40**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:53
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '12 Jan 2021'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:27:51

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:56:40**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:53
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 19:27:51

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:56:40**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:53
User entered empty.	System	20 Jan 2021 19:27:51

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:56:40**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:53
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:27:51

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:56:40**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:53
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'No (N)'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:27:51

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:56:40**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:53
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:27:51

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:56:40**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:53
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:27:51

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:56:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:53
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:27:51

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:56:40**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:53
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 19:27:51

US3062048

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:56:40

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:53
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 19:27:51

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:56:40**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:53
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 19:27:51

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:56:40**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:53
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 19:27:51

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:56:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:53
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:27:51

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:56:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:53
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:27:51

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:56:40**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:53
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:27:51

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:56:40**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:53
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:27:51

US3062048

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:56:40

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:53
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'Not Related (NOT RELATED)'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:27:51

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:56:40**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:53
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'Not Applicable (NOT APPLICABLE)'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:27:51

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:56:40**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:53
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'l'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:27:51

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:56:40**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:53
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:27:51

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:56:40**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:53
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered '0'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:27:51

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:56:40**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:53
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Riley King (b) (4) (b) (4)	20 Jan 2021 19:27:51

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:56:40**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:53
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 19:27:51

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:56:40**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:53
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:23:53
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 19:27:51

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:56:40**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:53
User entered '0'	System	20 Jan 2021 19:27:51

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:56:40**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:53
User entered '1'	System	20 Jan 2021 19:27:51

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 09 Jun 2021 14:56:40**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:32:53

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:56:40**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:02

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:56:40

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	16 Mar 2021 19:02:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Mar 2021 19:02:55
Data point term sent to Coder	System	16 Mar 2021 19:02:24
User entered 'Headache'	Riley King (b) (4)	16 Mar 2021 19:01:38

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:56:40**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
User entered 'Yes (Y)'	Riley King (b) (4)	16 Mar 2021 19:01:38

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:56:40**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
User entered 'No (N)'	Riley King (b) (4)	16 Mar 2021 19:01:38

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:56:40**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
User entered 'No (N)'	Riley King (b) (4)	16 Mar 2021 19:01:38

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
User entered '11 Jan 2021'	(b) (4) Riley King (b) (4) (b) (4)	16 Mar 2021 19:01:38

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:56:40**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
User entered empty.	Riley King (b) (4)	16 Mar 2021 19:01:38
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:56:40**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:02
User entered empty.	System	16 Mar 2021 19:01:38

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:56:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
User entered 'No (N)'	(b) (4) Riley King (b) (4) (b) (4)	16 Mar 2021 19:01:38

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:56:40**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
User entered '12 Jan 2021'	(b) (4) Riley King (b) (4) (b) (4)	16 Mar 2021 19:01:38

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:56:40**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	16 Mar 2021 19:01:38

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:56:40**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:02
User entered empty.	System	16 Mar 2021 19:01:38

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:56:40**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Riley King (b) (4)	16 Mar 2021 19:01:38
	(b) (4)	

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:56:40**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
User entered 'No (N)'	Riley King (b) (4)	16 Mar 2021 19:01:38

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:56:40**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
User entered '0'	Riley King (b) (4)	16 Mar 2021 19:01:38

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:56:40**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
User entered '0'	Riley King (b) (4)	16 Mar 2021 19:01:38

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:56:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
User entered '0'	Riley King (b) (4)	16 Mar 2021 19:01:38

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:56:40**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
User entered empty.	Riley King (b) (4)	16 Mar 2021 19:01:38

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:56:40**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	16 Mar 2021 19:01:38

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:56:40**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	16 Mar 2021 19:01:38

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:56:40**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
User entered empty.	Riley King (b) (4)	16 Mar 2021 19:01:38

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:56:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
User entered '0'	Riley King (b) (4)	16 Mar 2021 19:01:38

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:56:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
User entered '0'	Riley King (b) (4)	16 Mar 2021 19:01:38

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:56:40**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
User entered '0'	(b) (4) Riley King (b) (4) (b) (4)	16 Mar 2021 19:01:38

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:56:40**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
User entered 'Not Related (NOT RELATED)'	(b) (4) Riley King (b) (4) (b) (4)	16 Mar 2021 19:01:38

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:56:40**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
User entered 'Not Related (NOT RELATED)'	(b) (4) Riley King (b) (4) (b) (4)	16 Mar 2021 19:01:38

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:56:40**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Riley King (b) (4) (b) (4)	16 Mar 2021 19:01:38

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:56:40**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Riley King (b) (4)	31 Mar 2021 20:35:49
	(b) (4)	
User entered '0'	Riley King (b) (4)	16 Mar 2021 19:01:38
	(b) (4)	

US3062048

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 14:56:40

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 08:10:05
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'reconciled ' (Site from DM).	(b) (4)	
User entered '0' reason for change: Data Entry Error	Riley King (b) (4)	31 Mar 2021 20:36:09
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 11:17:59
User entered '1'	Riley King (b) (4)	16 Mar 2021 19:01:38

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:56:40**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
User entered '0'	Riley King (b) (4)	16 Mar 2021 19:01:38

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:56:40**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Riley King (b) (4) (b) (4)	16 Mar 2021 19:01:38

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:56:40**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
User entered empty.	Riley King (b) (4)	16 Mar 2021 19:01:38

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:56:40**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:39:57
User signature succeeded.	Richard Glover (b) (4)	31 Mar 2021 20:53:53
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	16 Mar 2021 19:01:38

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:56:40**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:02
User entered '0'	System	16 Mar 2021 19:01:38

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:56:40**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:02
User entered '1'	System	16 Mar 2021 19:01:38

**US3062048**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 09 Jun 2021 14:56:40**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:33:02

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:56:40

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:47:21
DataPoint Un-verified.		15 Feb 2021 19:27:33
DataPoint Verified.		15 Feb 2021 19:27:16
User entered 'Yes (Y)'	Sherry Henning (b) (4)	04 Aug 2020 21:42:50

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Aug 2020 21:45:08
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Aug 2020 21:45:08
	(b) (4)	
Data point term sent to Coder	System	04 Aug 2020 21:44:14
User entered 'Atorvastatin'	Sherry Henning (b) (4)	04 Aug 2020 21:43:49
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Sherry Henning (b) (4)	04 Aug 2020 21:43:49
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'hyperlipidemia'	Sherry Henning (b) (4)	04 Aug 2020 21:43:49
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '10'	Sherry Henning (b) (4)	04 Aug 2020 21:43:49
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'mg (mg)'	Sherry Henning (b) (4)	04 Aug 2020 21:43:49
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:56:40**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Sherry Henning (b) (4)	04 Aug 2020 21:43:49
	(b) (4)	

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:40

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'once daily (QD)'	Sherry Henning (b) (4)	04 Aug 2020 21:43:49
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:56:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Sherry Henning (b) (4)	04 Aug 2020 21:43:49
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Oral (ORAL)'	Sherry Henning (b) (4)	04 Aug 2020 21:43:49
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:56:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Sherry Henning (b) (4)	04 Aug 2020 21:43:49
	(b) (4)	

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:56:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
	(b) (4), (b) (6)	
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		10 Aug 2020 11:16:42
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Sherry Henning (b) (4)	04 Aug 2020 21:44:02
answered with 'correct as entered' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	04 Aug 2020 21:43:49
User entered '02 May 2016'	Sherry Henning (b) (4)	04 Aug 2020 21:43:49
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '0'	Sherry Henning (b) (4)	04 Aug 2020 21:43:49
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Yes (Y)'	Sherry Henning (b) (4)	04 Aug 2020 21:43:49
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:56:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Sherry Henning (b) (4)	04 Aug 2020 21:43:49
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Sherry Henning (b) (4)	04 Aug 2020 21:43:49
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 21:43:49

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 21:43:49

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Aug 2020 21:43:49

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Aug 2020 21:46:10
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Aug 2020 21:46:10
	(b) (4)	
Data point term sent to Coder	System	04 Aug 2020 21:45:19
User entered 'amlodipine'	Sherry Henning (b) (4)	04 Aug 2020 21:44:40
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:56:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Sherry Henning (b) (4)	04 Aug 2020 21:44:40
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:56:40**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'hypertension'	Sherry Henning (b) (4)	04 Aug 2020 21:44:40
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:56:40**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '5'	Sherry Henning (b) (4)	04 Aug 2020 21:44:40
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:56:40**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'mg (mg)'	Sherry Henning (b) (4)	04 Aug 2020 21:44:40
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:56:40**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Sherry Henning (b) (4)	04 Aug 2020 21:44:40
	(b) (4)	

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:40

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'once daily (QD)'	Sherry Henning (b) (4)	04 Aug 2020 21:44:40
	(b) (4)	

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Sherry Henning (b) (4)	04 Aug 2020 21:44:40
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:56:40**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Oral (ORAL)'	Sherry Henning (b) (4)	04 Aug 2020 21:44:40
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:56:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Sherry Henning (b) (4)	04 Aug 2020 21:44:40
	(b) (4)	

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:56:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
	(b) (4), (b) (6)	
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		10 Aug 2020 11:17:16
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Sherry Henning (b) (4)	04 Aug 2020 21:53:45
answered with 'correct as entered' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	04 Aug 2020 21:44:40
User entered 'un UNK 2016'	Sherry Henning (b) (4)	04 Aug 2020 21:44:40
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '0'	Sherry Henning (b) (4)	04 Aug 2020 21:44:40
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:56:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Yes (Y)'	Sherry Henning (b) (4)	04 Aug 2020 21:44:40
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:56:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Sherry Henning (b) (4)	04 Aug 2020 21:44:40
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:56:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Sherry Henning (b) (4)	04 Aug 2020 21:44:40
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:56:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 21:44:40

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 21:44:40

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Aug 2020 21:44:40

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: BENAZEPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Aug 2020 21:47:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Aug 2020 21:47:11
Data point term sent to Coder	System	04 Aug 2020 21:46:20
User entered 'benazepril'	Sherry Henning (b) (4) (b) (4)	04 Aug 2020 21:45:48

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:56:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Sherry Henning (b) (4)	04 Aug 2020 21:45:48
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:56:40**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'hypertension'	Sherry Henning (b) (4)	04 Aug 2020 21:45:48
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:56:40**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '10'	Sherry Henning (b) (4)	04 Aug 2020 21:45:48
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:56:40**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'mg (mg)'	Sherry Henning (b) (4)	04 Aug 2020 21:45:48
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:56:40**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Sherry Henning (b) (4)	04 Aug 2020 21:45:48
	(b) (4)	

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:40

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'once daily (QD)'	Sherry Henning (b) (4)	04 Aug 2020 21:45:48
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:56:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Sherry Henning (b) (4)	04 Aug 2020 21:45:48
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:56:40**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Oral (ORAL)'	Sherry Henning (b) (4)	04 Aug 2020 21:45:48
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:56:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Sherry Henning (b) (4)	04 Aug 2020 21:45:48
	(b) (4)	

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:56:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
	(b) (4), (b) (6)	
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		10 Aug 2020 11:17:36
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Sherry Henning (b) (4)	04 Aug 2020 21:46:18
answered with 'correct as entered' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	04 Aug 2020 21:45:48
User entered '29 Apr 2016'	Sherry Henning (b) (4)	04 Aug 2020 21:45:48
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '0'	Sherry Henning (b) (4)	04 Aug 2020 21:45:48
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:56:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Yes (Y)'	Sherry Henning (b) (4)	04 Aug 2020 21:45:48
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:56:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Sherry Henning (b) (4)	04 Aug 2020 21:45:48
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:56:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Sherry Henning (b) (4)	04 Aug 2020 21:45:48
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:56:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 21:45:48

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 21:45:48

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Aug 2020 21:45:48

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 09:50:21
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 09:50:21
Data point term sent to Coder	System	04 Aug 2020 21:47:25
User entered 'spironolactone'	Sherry Henning (b) (4) (b) (4)	04 Aug 2020 21:47:10

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:56:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Sherry Henning (b) (4)	04 Aug 2020 21:47:10
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:56:40**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'hypertension'	Sherry Henning (b) (4)	04 Aug 2020 21:47:10
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:56:40**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '25'	Sherry Henning (b) (4)	04 Aug 2020 21:47:10
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:56:40**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'mg (mg)'	Sherry Henning (b) (4)	04 Aug 2020 21:47:10
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:56:40**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Sherry Henning (b) (4)	04 Aug 2020 21:47:10
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:56:40**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'once daily (QD)'	Sherry Henning (b) (4)	04 Aug 2020 21:47:10
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:56:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Sherry Henning (b) (4)	04 Aug 2020 21:47:10
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:56:40**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Oral (ORAL)'	Sherry Henning (b) (4)	04 Aug 2020 21:47:10
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:56:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Sherry Henning (b) (4)	04 Aug 2020 21:47:10
	(b) (4)	

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:56:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
	(b) (4), (b) (6)	
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		10 Aug 2020 11:17:52
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Sherry Henning (b) (4)	04 Aug 2020 21:47:15
answered with 'correct as entered' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	04 Aug 2020 21:47:10
User entered 'un Jul 2018'	Sherry Henning (b) (4)	04 Aug 2020 21:47:10
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '0'	Sherry Henning (b) (4)	04 Aug 2020 21:47:10
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:56:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Yes (Y)'	Sherry Henning (b) (4)	04 Aug 2020 21:47:10
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:56:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Sherry Henning (b) (4)	04 Aug 2020 21:47:10
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:56:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Sherry Henning (b) (4)	04 Aug 2020 21:47:10
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:56:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 21:47:10

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 21:47:10

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Aug 2020 21:47:10

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: CHONDROITIN;GLUCOSAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Aug 2020 23:27:13
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 Aug 2020 23:27:13
Data point term sent to Coder	System	04 Aug 2020 21:48:26
User entered 'glucosamine chondroitin'	Sherry Henning (b) (4) (b) (4)	04 Aug 2020 21:48:25

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
	(b) (4), (b) (6)	
User closed query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM).		15 Sep 2020 07:34:54
Query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' answered with 'updated' (Site from DM).	marissa Mueller (b) (4)	14 Sep 2020 18:09:47
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	marissa Mueller (b) (4)	14 Sep 2020 18:09:24
	(b) (4)	
User opened query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 10:59:33
User entered 'No (N)'	Sherry Henning (b) (4)	04 Aug 2020 21:48:25
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:56:40**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'nutritional supplement'	Sherry Henning (b) (4)	04 Aug 2020 21:48:25
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:56:40**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '150'	Sherry Henning (b) (4)	04 Aug 2020 21:48:25
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:56:40**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'mg (mg)'	Sherry Henning (b) (4)	04 Aug 2020 21:48:25
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:56:40**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Sherry Henning (b) (4)	04 Aug 2020 21:48:25
	(b) (4)	

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:40

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'once daily (QD)'	Sherry Henning (b) (4)	04 Aug 2020 21:48:25
	(b) (4)	

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Sherry Henning (b) (4)	04 Aug 2020 21:48:25
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:56:40**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Oral (ORAL)'	Sherry Henning (b) (4)	04 Aug 2020 21:48:25
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:56:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Sherry Henning (b) (4)	04 Aug 2020 21:48:25
	(b) (4)	

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:56:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
	(b) (4), (b) (6)	
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		10 Aug 2020 11:18:06
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Sherry Henning (b) (4)	04 Aug 2020 21:51:09
answered with 'correct as entered' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	04 Aug 2020 21:48:25
User entered 'un UNK 2010'	Sherry Henning (b) (4)	04 Aug 2020 21:48:25
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '0'	Sherry Henning (b) (4)	04 Aug 2020 21:48:25
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:56:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Yes (Y)'	Sherry Henning (b) (4)	04 Aug 2020 21:48:25
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:56:40**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Sherry Henning (b) (4)	04 Aug 2020 21:48:25
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:56:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Sherry Henning (b) (4)	04 Aug 2020 21:48:25
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:56:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 21:48:25

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 21:48:25

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Aug 2020 21:48:25

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:56:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Aug 2020 21:53:09
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Aug 2020 21:53:09
	(b) (4)	
Data point term sent to Coder	System	04 Aug 2020 21:52:32
User entered 'multivitamin'	Sherry Henning (b) (4)	04 Aug 2020 21:51:49
	(b) (4)	

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:56:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
	(b) (4), (b) (6)	
User closed query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM).		15 Sep 2020 07:35:01
Query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' answered with 'updated' (Site from DM).	marissa Mueller (b) (4)	14 Sep 2020 18:10:27
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	marissa Mueller (b) (4)	14 Sep 2020 18:10:22
	(b) (4)	
User opened query 'Per CDM: It appears this medication was used for prophylaxis; however, Prophylaxis = No. Please review, reconcile and update accordingly.' (Site from DM).	(b) (4), (b) (6)	14 Sep 2020 10:59:51
User entered 'No (N)'	Sherry Henning (b) (4)	04 Aug 2020 21:51:49
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:56:40**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'nutritional supplement'	Sherry Henning (b) (4)	04 Aug 2020 21:51:49
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:56:40**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'I'	Sherry Henning (b) (4)	04 Aug 2020 21:51:49
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:56:40**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'tablet (TABLET)'	Sherry Henning (b) (4)	04 Aug 2020 21:51:49
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:56:40**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Sherry Henning (b) (4)	04 Aug 2020 21:51:49
	(b) (4)	

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:56:40

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'once daily (QD)'	Sherry Henning (b) (4)	04 Aug 2020 21:51:49
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:56:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Sherry Henning (b) (4)	04 Aug 2020 21:51:49
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:56:40**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Oral (ORAL)'	Sherry Henning (b) (4)	04 Aug 2020 21:51:49
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:56:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Sherry Henning (b) (4)	04 Aug 2020 21:51:49
	(b) (4)	

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:56:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
	(b) (4), (b) (6)	
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		10 Aug 2020 11:18:21
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Sherry Henning (b) (4)	04 Aug 2020 21:53:19
answered with 'correct as entered' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	04 Aug 2020 21:51:49
User entered 'un UNK 2005'	Sherry Henning (b) (4)	04 Aug 2020 21:51:49
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '0'	Sherry Henning (b) (4)	04 Aug 2020 21:51:49
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:56:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Yes (Y)'	Sherry Henning (b) (4)	04 Aug 2020 21:51:49
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:56:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Sherry Henning (b) (4)	04 Aug 2020 21:51:49
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:56:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Sherry Henning (b) (4)	04 Aug 2020 21:51:49
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:56:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 21:51:49

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 21:51:49

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Aug 2020 21:51:49

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:56:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 00:30:04
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 00:30:04
Data point term sent to Coder	System	04 Aug 2020 21:53:33
User entered 'ibuprofen'	Sherry Henning (b) (4) (b) (4)	04 Aug 2020 21:52:59

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:56:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Sherry Henning (b) (4)	04 Aug 2020 21:52:59
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:56:40**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'sciatica, left'	Sherry Henning (b) (4)	04 Aug 2020 21:52:59
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:56:40**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '800'	Sherry Henning (b) (4)	04 Aug 2020 21:52:59
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:56:40**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'mg (mg)'	Sherry Henning (b) (4)	04 Aug 2020 21:52:59
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:56:40**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Sherry Henning (b) (4)	04 Aug 2020 21:52:59
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:56:40**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'as needed (PRN)'	Sherry Henning (b) (4)	04 Aug 2020 21:52:59
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:56:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Sherry Henning (b) (4)	04 Aug 2020 21:52:59
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:56:40**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Oral (ORAL)'	Sherry Henning (b) (4)	04 Aug 2020 21:52:59
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:56:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Sherry Henning (b) (4)	04 Aug 2020 21:52:59
	(b) (4)	

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:56:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
	(b) (4), (b) (6)	
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).		10 Aug 2020 11:18:37
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Sherry Henning (b) (4)	04 Aug 2020 21:53:06
answered with 'correct as entered' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	04 Aug 2020 21:52:59
User entered 'un UNK 2001'	Sherry Henning (b) (4)	04 Aug 2020 21:52:59
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '0'	Sherry Henning (b) (4)	04 Aug 2020 21:52:59
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:56:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Yes (Y)'	Sherry Henning (b) (4)	04 Aug 2020 21:52:59
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:56:40**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Sherry Henning (b) (4)	04 Aug 2020 21:52:59
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:56:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Sherry Henning (b) (4)	04 Aug 2020 21:52:59
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:56:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Aug 2020 21:52:59

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Aug 2020 21:52:59

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Aug 2020 21:52:59

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:56:40

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
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: DICLOFENAC SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 21:11:08
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 21:11:08
Data point term sent to Coder	System	20 Jan 2021 17:56:43
User entered 'Diclofenac sodium'	Riley King (b) (4) (b) (4)	20 Jan 2021 17:56:39

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:56:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Riley King (b) (4)	20 Jan 2021 17:56:39
	(b) (4)	

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:56:40

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history of SCIATIA, LEFT worsened. If yes, please review if an AE of Worsening SCIATIA, LEFT should be recorded, and update con med indication or provide clarification. ' (Site from DM).		26 Feb 2021 06:56:01
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history of SCIATIA, LEFT worsened. If yes, please review if an AE of Worsening SCIATIA, LEFT should be recorded, and update con med indication or provide clarification. ' answered with 'correct as entered' (Site from DM).	marissa Mueller (b) (4)	12 Feb 2021 17:42:39
	(b) (4)	
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history of SCIATIA, LEFT worsened. If yes, please review if an AE of Worsening SCIATIA, LEFT should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 07:46:06
User entered 'Low back pain'	Riley King (b) (4)	20 Jan 2021 17:56:39
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:56:40**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '75'	Riley King (b) (4)	20 Jan 2021 17:56:39
	(b) (4)	

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:56:40

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'mg (mg)'	Riley King (b) (4)	20 Jan 2021 17:56:39
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:56:40**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4)	20 Jan 2021 17:56:39
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:56:40**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'twice daily (BID)'	Riley King (b) (4)	20 Jan 2021 17:56:39
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:56:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4)	20 Jan 2021 17:56:39
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:56:40**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Oral (ORAL)'	Riley King (b) (4)	20 Jan 2021 17:56:39
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:56:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4)	20 Jan 2021 17:56:39
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '05 Nov 2020'	Riley King (b) (4)	20 Jan 2021 17:56:39
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '0'	Riley King (b) (4)	20 Jan 2021 17:56:39
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:56:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Yes (Y)'	Riley King (b) (4)	20 Jan 2021 17:56:39
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:56:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4)	20 Jan 2021 17:56:39
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:56:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Riley King (b) (4)	20 Jan 2021 17:56:39
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:56:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Jan 2021 17:56:39

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Jan 2021 17:56:39

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Jan 2021 17:56:39

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:56:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
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)	20 Jan 2021 20:55:11
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 20:55:11
	(b) (4)	
Data point term sent to Coder	System	20 Jan 2021 17:57:43
User entered 'Cyclobenzapine'	Riley King (b) (4)	20 Jan 2021 17:57:35
	(b) (4)	

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 14:56:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Riley King (b) (4)	20 Jan 2021 17:57:35
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:56:40**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Low back pain'	Riley King (b) (4)	20 Jan 2021 17:57:35
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:56:40**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '10'	Riley King (b) (4)	20 Jan 2021 17:57:35
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:56:40**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'mg (mg)'	Riley King (b) (4)	20 Jan 2021 17:57:35
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:56:40**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4)	20 Jan 2021 17:57:35
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:56:40**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'three times daily (TID)'	Riley King (b) (4)	20 Jan 2021 17:57:35
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:56:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4)	20 Jan 2021 17:57:35
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:56:40**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Oral (ORAL)'	Riley King (b) (4)	20 Jan 2021 17:57:35
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:56:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4)	20 Jan 2021 17:57:35
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '05 Nov 2020'	Riley King (b) (4)	20 Jan 2021 17:57:35
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '0'	Riley King (b) (4)	20 Jan 2021 17:57:35
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:56:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Yes (Y)'	Riley King (b) (4)	20 Jan 2021 17:57:35
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:56:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4)	20 Jan 2021 17:57:35
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:56:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Riley King (b) (4)	20 Jan 2021 17:57:35
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:56:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	20 Jan 2021 17:57:35

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Jan 2021 17:57:35

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Jan 2021 17:57:35

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:56:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: SALICYLIC ACID AND DERIVATIVES, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ECOTRIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 21:13:09
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 Jan 2021 21:13:09
Data point term sent to Coder	System	20 Jan 2021 17:58:44
User entered 'Ecotrin'	Riley King (b) (4) (b) (4)	20 Jan 2021 17:58:31

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:56:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Riley King (b) (4) (b) (4)	20 Jan 2021 17:58:31

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:56:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Lumbar radiculopathy involving the left S1 nerve root'	Riley King (b) (4) (b) (4)	20 Jan 2021 17:58:31

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:56:40**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '81'	Riley King (b) (4)	20 Jan 2021 17:58:31

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:56:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'mg (mg)'	Riley King (b) (4) (b) (4)	20 Jan 2021 17:58:31

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:56:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 17:58:31

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:56:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'twice daily (BID)'	Riley King (b) (4)	20 Jan 2021 17:58:31

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:56:40

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 17:58:31

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:56:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Oral (ORAL)'	Riley King (b) (4)	20 Jan 2021 17:58:31

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:56:40

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4)	20 Jan 2021 17:58:31

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:56:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4)	01 Mar 2021 20:50:49
User entered '12 Jan 2021' reason for change: Data Entry Error	Riley King (b) (4)	24 Feb 2021 16:57:45
User entered '21 Jan 2021' reason for change: Data Entry Error	Riley King (b) (4)	24 Feb 2021 16:57:28
User entered '12 Jan 2021'	Riley King (b) (4)	20 Jan 2021 17:58:31

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4)	01 Mar 2021 20:50:49
User entered '0'	Riley King (b) (4)	20 Jan 2021 17:58:31

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:56:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4)	01 Mar 2021 20:50:49
User closed query 'Per CDM, DM CLR re-query: Response noted. At the next patient contact, please review if a stop date should be recorded, else provide clarification for continued used of medication. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 14:50:28
Query 'Per CDM, DM CLR re-query: Response noted. At the next patient contact, please review if a stop date should be recorded, else provide clarification for continued used of medication. ' answered with 'Stop date recorded ' (Site from DM).	Riley King (b) (4)	24 Feb 2021 16:58:01
User entered 'No (N)' reason for change: Per Query Resolution	Riley King (b) (4)	24 Feb 2021 16:57:28
User opened query 'Per CDM, DM CLR re-query: Response noted. At the next patient contact, please review if a stop date should be recorded, else provide clarification for continued used of medication. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 09:22:35
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 09:22:35
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'NO STOP DATE PER SOURCE DOCUMENTATION' (Site from DM).	Janna Martinez (b) (4)	22 Feb 2021 21:26:23
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 07:46:28

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:56:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Riley King (b) (4) (b) (4)	20 Jan 2021 17:58:31

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:56:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User closed query 'Per DM CLR: The corresponding AE has resolved ON 12 JAN 2021 , however the medication ended on 21 JAN 2021. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Mar 2021 06:01:25
Query 'Per DM CLR: The corresponding AE has resolved ON 12 JAN 2021 , however the medication ended on 21 JAN 2021. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' answered with 'reconciled ' (Site from DM).	Riley King (b) (4) (b) (4)	11 Mar 2021 16:59:06
DataPoint Un-verified.	Riley King (b) (4) (b) (4)	11 Mar 2021 16:58:55
User entered '12 Jan 2021' reason for change: Data Entry Error	Riley King (b) (4) (b) (4)	11 Mar 2021 16:58:55
User opened query 'Per DM CLR: The corresponding AE has resolved ON 12 JAN 2021 , however the medication ended on 21 JAN 2021. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 07:37:46
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	24 Feb 2021 16:57:45
User entered '21 Jan 2021' reason for change: Data Entry Error	Riley King (b) (4) (b) (4)	24 Feb 2021 16:57:45
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	24 Feb 2021 16:57:28
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 17:58:31

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 14:56:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Riley King (b) (4) (b) (4)	20 Jan 2021 17:58:31

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:56:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:29
User entered '2'	System	20 Jan 2021 17:58:31

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:29
User entered '1'	System	20 Jan 2021 17:58:31

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:29
User entered '804 (804)'	System	20 Jan 2021 17:58:31

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:56:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4)	01 Mar 2021 20:50:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL HYDROCHLORIDE, PRODUCTSYNONYM: ULTRAM [TRAMADOL HYDROCHLORIDE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Jan 2021 22:08:23
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Jan 2021 22:08:23
Data point term sent to Coder	System	20 Jan 2021 17:59:45
User entered 'Ultram(tramadol)'	Riley King (b) (4)	20 Jan 2021 17:59:07

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:56:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Riley King (b) (4)	20 Jan 2021 17:59:07

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:56:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Lumbar radiculopathy involving the left S1 nerve root'	Riley King (b) (4) (b) (4)	20 Jan 2021 17:59:07

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:56:40**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '50'	Riley King (b) (4)	20 Jan 2021 17:59:07

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:56:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'mg (mg)'	Riley King (b) (4)	20 Jan 2021 17:59:07

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:56:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 17:59:07

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:56:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'as needed (PRN)'	Riley King (b) (4)	20 Jan 2021 17:59:07
	(b) (4)	

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:56:40

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4)	20 Jan 2021 17:59:07

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:56:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Oral (ORAL)'	Riley King (b) (4)	20 Jan 2021 17:59:07

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:56:40

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4)	20 Jan 2021 17:59:07
	(b) (4)	

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:56:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '12 Jan 2021'	Riley King (b) (4)	20 Jan 2021 17:59:07

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '0'	Riley King (b) (4)	20 Jan 2021 17:59:07

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:56:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User closed query 'Per CDM, DM CLR re-query: Response noted. At the next patient contact, please review if a stop date should be recorded, else provide clarification for continued used of medication. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 15:07:26
Query 'Per CDM, DM CLR re-query: Response noted. At the next patient contact, please review if a stop date should be recorded, else provide clarification for continued used of medication. ' answered with 'end date added ' (Site from DM).	Riley King (b) (4) (b) (4)	24 Feb 2021 16:58:53
User entered 'No (N)' reason for change: Data Entry Error	Riley King (b) (4) (b) (4)	24 Feb 2021 16:58:42
User opened query 'Per CDM, DM CLR re-query: Response noted. At the next patient contact, please review if a stop date should be recorded, else provide clarification for continued used of medication. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 09:23:02
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 09:23:02
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'NO STOP DATE PER SOURCE' (Site from DM).	Janna Martinez (b) (4) (b) (4)	22 Feb 2021 21:27:07
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 07:46:40

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:56:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Riley King (b) (4) (b) (4)	20 Jan 2021 17:59:07

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:56:40

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User closed query 'Per DM CLR: The corresponding AE has resolved ON 12 JAN 2021 , however the medication ended on 21 JAN 2021. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4)	15 Mar 2021 06:07:58
Query 'Per DM CLR: The corresponding AE has resolved ON 12 JAN 2021 , however the medication ended on 21 JAN 2021. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' answered with 'reconciled ' (Site from DM).	Riley King (b) (4)	11 Mar 2021 16:59:57
DataPoint Un-verified.	(b) (4)	11 Mar 2021 16:59:48
User entered '12 Jan 2021' reason for change: Data Entry Error	Riley King (b) (4)	11 Mar 2021 16:59:48
User opened query 'Per DM CLR: The corresponding AE has resolved ON 12 JAN 2021 , however the medication ended on 21 JAN 2021. Please verify and update stop date for this Con Med and/or AE as appropriate. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 07:38:14
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '21 Jan 2021' reason for change: Data Entry Error	Riley King (b) (4)	24 Feb 2021 16:58:42
User entered empty.	(b) (4)	20 Jan 2021 17:59:07

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 14:56:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:49
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Riley King (b) (4)	20 Jan 2021 17:59:07

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:56:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:49
User entered empty.	System	20 Jan 2021 17:59:07

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:49
User entered empty.	System	20 Jan 2021 17:59:07

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:49
User entered empty.	System	20 Jan 2021 17:59:07

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:56:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 18:15:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 18:15:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 18:00:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 18:00:06
Data point term sent to Coder	System	20 Jan 2021 17:59:45
User entered 'Tylenol'	Riley King (b) (4) (b) (4)	20 Jan 2021 17:59:42

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:56:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Riley King (b) (4) (b) (4)	20 Jan 2021 17:59:42

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:56:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Lumbar radiculopathy involving the left S1 nerve root'	Riley King (b) (4) (b) (4)	20 Jan 2021 17:59:42

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:56:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '650'	Riley King (b) (4)	20 Jan 2021 17:59:42
	(b) (4)	

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:56:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'mg (mg)'	Riley King (b) (4) (b) (4)	20 Jan 2021 17:59:42

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:56:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 17:59:42

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:56:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'as needed (PRN)'	Riley King (b) (4) (b) (4)	20 Jan 2021 17:59:42

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:56:40

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4)	20 Jan 2021 17:59:42

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:56:40

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Oral (ORAL)'	Riley King (b) (4) (b) (4)	20 Jan 2021 17:59:42

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:56:40

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4)	20 Jan 2021 17:59:42

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:56:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '11 Jan 2021'	Riley King (b) (4)	20 Jan 2021 17:59:42

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '0'	Riley King (b) (4)	20 Jan 2021 17:59:42

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:56:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Riley King (b) (4) (b) (4)	20 Jan 2021 17:59:42

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 14:56:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '11 Jan 2021'	Riley King (b) (4) (b) (4)	20 Jan 2021 17:59:42

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:56:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:58
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Riley King (b) (4) (b) (4)	20 Jan 2021 17:59:42

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:56:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:58
User entered empty.	System	20 Jan 2021 17:59:42

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:58
User entered empty.	System	20 Jan 2021 17:59:42

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:24:58
User entered empty.	System	20 Jan 2021 17:59:42

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:56:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:14
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 17:05:06
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 17:05:06
User signature succeeded.	Troy Holdeman (b) (4) (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
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)	20 Jan 2021 21:46:08
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 21:46:08
Data point term sent to Coder	System	20 Jan 2021 18:00:51
User entered 'Normal saline'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:00:33

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:56:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:00:33

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:56:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Lumbar radiculopathy involving the left S1 nerve root'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:00:33

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:56:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '1000'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:00:33

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:56:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'mL (mL)'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:00:33

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:56:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4)	20 Jan 2021 18:00:33

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:56:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'other (OTHER)'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:00:33

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:56:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '200 mL/hour'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:00:33

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:56:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	20 Jan 2021 18:00:33

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:56:40

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 18:00:33

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '11 Jan 2021'	Riley King (b) (4)	20 Jan 2021 18:00:33

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '0'	Riley King (b) (4)	20 Jan 2021 18:00:33

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:56:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:00:33

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 14:56:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '11 Jan 2021'	Riley King (b) (4)	20 Jan 2021 18:00:33

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:56:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:14
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Riley King (b) (4)	20 Jan 2021 18:00:33

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:56:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:14
User entered empty.	System	20 Jan 2021 18:00:33

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:14
User entered empty.	System	20 Jan 2021 18:00:33

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:14
User entered empty.	System	20 Jan 2021 18:00:33

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:56:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: OTHER NASAL PREPARATIONS, PRODUCT: ETHANOL, PRODUCTSYNONYM: NOZIN NASAL SANITIZER - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 21:51:12
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 Jan 2021 21:51:12
Data point term sent to Coder	System	20 Jan 2021 18:01:54
User entered 'Nozin nasal swab'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:01:14

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:56:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:01:14

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:56:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Lumbar radiculopathy involving the left S1 nerve root'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:01:14

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:56:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '2'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:01:14

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:56:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Other (OTHER)'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:01:14

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:56:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Swab'	Riley King (b) (4)	20 Jan 2021 18:01:14

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:56:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'once (ONCE)'	Riley King (b) (4)	20 Jan 2021 18:01:14

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:56:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 18:01:14

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:56:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Nasal (NASAL)'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:01:14

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 14:56:40

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 18:01:14

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '11 Jan 2021'	Riley King (b) (4)	20 Jan 2021 18:01:14

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '0'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:01:14

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:56:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:01:14

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:56:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '11 Jan 2021'	Riley King (b) (4)	20 Jan 2021 18:01:14

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:56:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:28
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:01:14

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:56:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:28
User entered empty.	System	20 Jan 2021 18:01:14

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:28
User entered empty.	System	20 Jan 2021 18:01:14

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:28
User entered empty.	System	20 Jan 2021 18:01:14

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:56:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4)	01 Mar 2021 20:50:49
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 22:09:08
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 22:09:08
Data point term sent to Coder	System	20 Jan 2021 18:01:54
User entered 'Vancomycin'	Riley King (b) (4)	20 Jan 2021 18:01:53

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:56:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:01:53

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:56:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Lumbar radiculopathy involving the left S1 nerve root'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:01:53

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:56:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '1000'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:01:53

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:56:40**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'mg (mg)'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:01:53

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:56:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 18:01:53

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:56:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'once (ONCE)'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:01:53

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:56:40

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4)	20 Jan 2021 18:01:53

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:56:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:01:53

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:56:40

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 18:01:53

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '11 Jan 2021'	Riley King (b) (4)	20 Jan 2021 18:01:53

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '0'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:01:53

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:56:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:01:53

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 14:56:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '11 Jan 2021'	Riley King (b) (4)	20 Jan 2021 18:01:53

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:56:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:38
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Riley King (b) (4)	20 Jan 2021 18:01:53

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:56:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:38
User entered empty.	System	20 Jan 2021 18:01:53

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:38
User entered empty.	System	20 Jan 2021 18:01:53

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:38
User entered empty.	System	20 Jan 2021 18:01:53

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:56:40

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIHEMORRHAGICS, ATC: VITAMIN K AND OTHER HEMOSTATICS, ATC: BLOOD COAGULATION FACTORS, PRODUCT: THROMBIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 06:12:38
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 06:12:38
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
Data point term sent to Coder	System	21 Jan 2021 17:55:10
User closed query 'For coding purposes, please provide the trade name for this combo, if not a marketed combo then please split into separate entries, one drug per line, and update the term accordingly' (Site from System).	System	21 Jan 2021 17:54:58
Query 'For coding purposes, please provide the trade name for this combo, if not a marketed combo then please split into separate entries, one drug per line, and update the term accordingly' answered with 'Medication name updated.' (Site from System).	Riley King (b) (4)	21 Jan 2021 17:54:58
User entered 'THROMBIN' reason for change: Per Query Resolution	Riley King (b) (4)	21 Jan 2021 17:54:31
User opened query 'For coding purposes, please provide the trade name for this combo, if not a marketed combo then please split into separate entries, one drug per line, and update the term accordingly' (Site from System).	Coder Import (b) (4)	20 Jan 2021 22:08:18
Data point term sent to Coder	System	20 Jan 2021 18:02:55
User entered 'Thrombin/surgiFlo'	Riley King (b) (4)	20 Jan 2021 18:02:44

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:56:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Riley King (b) (4)	20 Jan 2021 18:02:44
	(b) (4)	

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:56:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Lumbar radiculopathy involving the left S1 nerve root'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:02:44

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:56:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '10000'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:02:44

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:56:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Other (OTHER)'	Riley King (b) (4)	20 Jan 2021 18:02:44

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:56:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Units'	Riley King (b) (4)	20 Jan 2021 18:02:44

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:56:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'once (ONCE)'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:02:44

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:56:40

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4)	20 Jan 2021 18:02:44

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:56:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	20 Jan 2021 18:02:44

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:56:40

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4)	20 Jan 2021 18:02:44

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '11 Jan 2021'	Riley King (b) (4)	20 Jan 2021 18:02:44

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '0'	Riley King (b) (4)	20 Jan 2021 18:02:44

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:56:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Riley King (b) (4)	20 Jan 2021 18:02:44

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 14:56:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '11 Jan 2021'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:02:44

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:56:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:54
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Riley King (b) (4)	20 Jan 2021 18:02:44

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:56:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:54
User entered empty.	System	20 Jan 2021 18:02:44

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:54
User entered empty.	System	20 Jan 2021 18:02:44

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:25:54
User entered empty.	System	20 Jan 2021 18:02:44

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:56:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:26:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4)	01 Mar 2021 20:50:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: BUPIVACAINE, PRODUCTSYNONYM: MARCAINE [BUPIVACAINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 21:45:09
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 21:45:09
Data point term sent to Coder	System	20 Jan 2021 18:03:56
User entered 'Marcaine 0.5%'	Riley King (b) (4)	20 Jan 2021 18:03:28
	(b) (4)	

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:56:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:26:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Riley King (b) (4)	20 Jan 2021 18:03:28

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:56:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:26:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Lumbar radiculopathy involving the left S1 nerve root'	Riley King (b) (4)	20 Jan 2021 18:03:28

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:56:40**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:26:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '30'	Riley King (b) (4)	20 Jan 2021 18:03:28

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:56:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:26:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'mL (mL)'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:03:28

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 14:56:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:26:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4)	20 Jan 2021 18:03:28

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:56:40**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:26:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'once (ONCE)'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:03:28

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:56:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:26:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 18:03:28

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:56:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:26:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:03:28

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:56:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:26:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4)	20 Jan 2021 18:03:28

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:26:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '11 Jan 2021'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:03:28

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:26:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '0'	Riley King (b) (4)	20 Jan 2021 18:03:28

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:56:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:26:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Riley King (b) (4)	20 Jan 2021 18:03:28

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:56:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:26:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '11 Jan 2021'	Riley King (b) (4)	20 Jan 2021 18:03:28

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:56:40**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:26:05
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Riley King (b) (4)	20 Jan 2021 18:03:28

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:56:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:26:05
User entered empty.	System	20 Jan 2021 18:03:28

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:26:05
User entered empty.	System	20 Jan 2021 18:03:28

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:26:05
User entered empty.	System	20 Jan 2021 18:03:28

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:56:40

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 00:15:32
User closed query 'please enter as lactated ringers solution per source' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 00:15:29
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: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 13:53:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 13:53:58
Data point term sent to Coder	System	03 Mar 2021 13:53:34
Query 'please enter as lactated ringers solution per source' answered with 'reconciled ' (Site from CRA).	Riley King (b) (4) (b) (4)	03 Mar 2021 13:53:33
Coding entries removed.	Riley King (b) (4) (b) (4)	03 Mar 2021 13:53:25
User entered 'lactated ringers' reason for change: Data Entry Error	Riley King (b) (4) (b) (4)	03 Mar 2021 13:53:25
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 20:51:34
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User opened query 'please enter as lactated ringers solution per source' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 20:49:05

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:56:40

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), COMBINATIONS, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), OTHER COMBINATIONS, PRODUCT: LOSARTAN POTASSIUM;RAMIPRIL, PRODUCTSYNONYM: LR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 18:06:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 18:06:15
Data point term sent to Coder	System	20 Jan 2021 18:04:56
User entered 'LR'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:04:11

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:56:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Riley King (b) (4)	20 Jan 2021 18:04:11

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:56:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Lumbar radiculopathy involving the left S1 nerve root'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:04:11

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:56:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '1000'	Riley King (b) (4)	20 Jan 2021 18:04:11

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:56:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'mL (mL)'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:04:11

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:56:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 18:04:11

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:56:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'other (OTHER)'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:04:11

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:56:40

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '50 mL/hour'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:04:11

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 14:56:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:04:11

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:56:40

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 18:04:11

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:56:40

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '11 Jan 2021'	Riley King (b) (4)	20 Jan 2021 18:04:11

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '0'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:04:11

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 14:56:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Riley King (b) (4)	20 Jan 2021 18:04:11

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:56:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '11 Jan 2021'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:04:11

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 14:56:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:09
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Riley King (b) (4)	20 Jan 2021 18:04:11

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 14:56:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:09
User entered empty.	System	20 Jan 2021 18:04:11

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:09
User entered empty.	System	20 Jan 2021 18:04:11

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:09
User entered empty.	System	20 Jan 2021 18:04:11

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:56:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN SODIUM, PRODUCTSYNONYM: KEFZOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 18:06:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Jan 2021 18:06:16
Data point term sent to Coder	System	20 Jan 2021 18:04:56
User entered 'KefZol'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:04:52

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:56:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:04:52

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:56:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Lumbar radiculopathy involving the left S1 nerve root'	Riley King (b) (4)	20 Jan 2021 18:04:52

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:56:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4)	01 Mar 2021 20:50:49
User entered '2'	Riley King (b) (4)	20 Jan 2021 18:04:52

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 14:56:40**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'g (g)'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:04:52

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:56:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4)	20 Jan 2021 18:04:52

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:56:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'once (ONCE)'	Riley King (b) (4)	20 Jan 2021 18:04:52

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 14:56:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 18:04:52

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 14:56:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:04:52

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:56:40

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4)	20 Jan 2021 18:04:52

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '11 Jan 2021'	Riley King (b) (4)	20 Jan 2021 18:04:52

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '0'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:04:52

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 14:56:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:04:52

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:56:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '11 Jan 2021'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:04:52

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 14:56:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:24
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Riley King (b) (4)	20 Jan 2021 18:04:52

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 14:56:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:24
User entered empty.	System	20 Jan 2021 18:04:52

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:24
User entered empty.	System	20 Jan 2021 18:04:52

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:24
User entered empty.	System	20 Jan 2021 18:04:52

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:56:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4)	01 Mar 2021 20:50:49
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE ACETATE, PRODUCTSYNONYM: DEPO MEDROL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 21:07:08
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 21:07:08
Data point term sent to Coder	System	20 Jan 2021 18:06:59
User entered 'Depo-Medrol'	Riley King (b) (4)	20 Jan 2021 18:05:58

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 14:56:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:05:58

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:56:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Low back pain'	Riley King (b) (4)	20 Jan 2021 18:05:58

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:56:40

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '80'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:05:58

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:56:40

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4)	01 Mar 2021 20:50:49
User entered 'mg (mg)'	Riley King (b) (4)	20 Jan 2021 18:05:58

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:56:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 18:05:58

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:56:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4)	01 Mar 2021 20:50:49
User entered 'once (ONCE)'	Riley King (b) (4)	20 Jan 2021 18:05:58

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:56:40

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4) (b) (4)	20 Jan 2021 18:05:58

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:56:40

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Other (OTHER)'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:05:58

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:56:40

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'Epidural'	Riley King (b) (4)	20 Jan 2021 18:05:58

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '05 Nov 2020'	Riley King (b) (4)	20 Jan 2021 18:05:58

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '0'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:05:58

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 14:56:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Riley King (b) (4)	20 Jan 2021 18:05:58

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:56:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '05 Nov 2020'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:05:58

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 14:56:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Riley King (b) (4) (b) (4)	20 Jan 2021 18:05:58

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 14:56:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:34
User entered empty.	System	20 Jan 2021 18:05:58

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:34
User entered empty.	System	20 Jan 2021 18:05:58

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:34
User entered empty.	System	20 Jan 2021 18:05:58

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:56:40

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4)	01 Mar 2021 20:50:49
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM, ATC: OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM, ATC: OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM, PRODUCT: GELATIN, PRODUCTSYNONYM: SURGIFLO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Jan 2021 06:02:14
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Jan 2021 06:02:14
Data point term sent to Coder	System	21 Jan 2021 17:57:15
User entered 'Surgiflo'	Riley King (b) (4)	21 Jan 2021 17:56:13

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:56:40

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Riley King (b) (4) (b) (4)	21 Jan 2021 17:56:13

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:56:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'LUMBAR RADICULOPATHY INVOLVING THE LEFT S1 NERVE ROOT'	Riley King (b) (4) (b) (4)	21 Jan 2021 17:56:13

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 14:56:40**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '8'	Riley King (b) (4) (b) (4)	21 Jan 2021 17:56:13

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 14:56:40**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'mL (mL)'	Riley King (b) (4) (b) (4)	21 Jan 2021 17:56:13

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:56:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4) (b) (4)	21 Jan 2021 17:56:13

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:56:40

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'once (ONCE)'	Riley King (b) (4) (b) (4)	21 Jan 2021 17:56:13

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 14:56:40**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4) (b) (4)	21 Jan 2021 17:56:13

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 14:56:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4)	01 Mar 2021 20:50:49
User entered 'Intravenous (INTRAVENOUS)'	Riley King (b) (4)	21 Jan 2021 17:56:13

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 14:56:40**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered empty.	Riley King (b) (4)	21 Jan 2021 17:56:13

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:56:40

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '11 Jan 2021'	Riley King (b) (4)	21 Jan 2021 17:56:13

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '0'	Riley King (b) (4)	21 Jan 2021 17:56:13

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:56:40

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Riley King (b) (4) (b) (4)	21 Jan 2021 17:56:13

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:56:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered '11 Jan 2021'	Riley King (b) (4) (b) (4)	21 Jan 2021 17:56:13

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 14:56:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:43
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:50:49
User entered 'No (N)'	Riley King (b) (4) (b) (4)	21 Jan 2021 17:56:13

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 14:56:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:43
User entered empty.	System	21 Jan 2021 17:56:13

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:43
User entered empty.	System	21 Jan 2021 17:56:13

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:27:43
User entered empty.	System	21 Jan 2021 17:56:13

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:56:40

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:28:01
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OTHER DRUGS FOR CONSTIPATION, PRODUCT: OTHER DRUGS FOR CONSTIPATION - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 10:01:31
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 Apr 2021 10:01:31
User signature succeeded.	Troy Holdeman (b) (4) (b) (4)	02 Apr 2021 20:20:55
Data point term sent to Coder	System	18 Mar 2021 16:43:03
User closed query 'CDM-Coding: The trade name DURASEAL GLUE cannot be referred in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' (Site from System).	System	18 Mar 2021 16:42:44
Query 'CDM-Coding: The trade name DURASEAL GLUE cannot be referred in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' answered with 'Reconciled ' (Site from System).	Riley King (b) (4) (b) (4)	18 Mar 2021 16:42:44
User entered 'Polyethylene Glycol Ester and Trilysine Amine solution' reason for change: Data Entry Error	Riley King (b) (4) (b) (4)	18 Mar 2021 16:42:30
User opened query 'CDM-Coding: The trade name DURASEAL GLUE cannot be referred in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. ' (Site from System).	Coder Import (b) (4) (b) (4)	17 Mar 2021 09:38:41
Data point term sent to Coder	System	11 Mar 2021 16:54:43
User entered 'Duraseal glue'	Riley King (b) (4) (b) (4)	11 Mar 2021 16:54:41

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 14:56:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:28:01
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered 'No (N)'	Riley King (b) (4)	11 Mar 2021 16:54:41

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 14:56:40**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:28:01
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered 'incidental durotomy'	(b) (4) Riley King (b) (4) (b) (4)	11 Mar 2021 16:54:41

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 14:56:40**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:28:01
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered 'I'	(b) (4) Riley King (b) (4) (b) (4)	11 Mar 2021 16:54:41

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 14:56:40**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:28:01
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
User entered 'Other (OTHER)'	Riley King (b) (4)	11 Mar 2021 16:54:41
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 14:56:40**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:28:01
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered 'application'	(b) (4) Riley King (b) (4) (b) (4)	11 Mar 2021 16:54:41

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 14:56:40**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:28:01
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered 'once (ONCE)'	(b) (4) Riley King (b) (4) (b) (4)	11 Mar 2021 16:54:41

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:56:40

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:28:01
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
User entered empty.	Riley King (b) (4)	11 Mar 2021 16:54:41
	(b) (4)	

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:56:40

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:28:01
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
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)	01 Apr 2021 08:09:08
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'This was used to seal surgical opening during this procedure. Which makes this administered topically. ' (Site from DM).	Riley King (b) (4) (b) (4)	31 Mar 2021 20:34:38
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)	29 Mar 2021 10:13:12
User entered 'Topical (TOPICAL)'	Riley King (b) (4) (b) (4)	11 Mar 2021 16:54:41

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:56:40

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:28:01
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
User entered empty.	Riley King (b) (4)	11 Mar 2021 16:54:41
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:28:01
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered '11 Jan 2021'	(b) (4) Riley King (b) (4) (b) (4)	11 Mar 2021 16:54:41

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:28:01
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered '0'	Riley King (b) (4)	11 Mar 2021 16:54:41

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 14:56:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:28:01
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered 'No (N)'	(b) (4) Riley King (b) (4) (b) (4)	11 Mar 2021 16:54:41

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 14:56:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:28:01
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered '11 Jan 2021'	(b) (4) Riley King (b) (4) (b) (4)	11 Mar 2021 16:54:41

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 14:56:40

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:28:01
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 08:09:30
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'updated' (Site from DM).	marissa Mueller (b) (4)	31 Mar 2021 19:50:14
User entered 'No (N)' reason for change: Data Entry Error	marissa Mueller (b) (4)	31 Mar 2021 19:50:11
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Mar 2021 10:13:20
User entered 'Yes (Y)'	Riley King (b) (4) (b) (4)	11 Mar 2021 16:54:41

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 14:56:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:28:01
User entered empty.	System	11 Mar 2021 16:54:41

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:28:01
User entered empty.	System	11 Mar 2021 16:54:41

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:28:01
User entered empty.	System	11 Mar 2021 16:54:41

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:56:40

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:28:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Mar 2021 12:14:42
User coded data point as Term Coded data point by User (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 12:14:42
Data point term sent to Coder	System	16 Mar 2021 19:18:41
User entered 'methylprednisone'	Riley King (b) (4) (b) (4)	16 Mar 2021 19:17:41

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 14:56:40**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:28:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered 'No (N)'	Riley King (b) (4)	16 Mar 2021 19:17:41

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 14:56:40**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:28:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered 'low back pain'	Riley King (b) (4)	16 Mar 2021 19:17:41

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 14:56:40**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:28:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered '80'	(b) (4) Riley King (b) (4) (b) (4)	16 Mar 2021 19:17:41

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 14:56:40**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:28:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
User entered 'mg (mg)'	Riley King (b) (4)	16 Mar 2021 19:17:41
	(b) (4)	

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:56:40

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:28:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered empty.	(b) (4) Riley King (b) (4) (b) (4)	16 Mar 2021 19:17:41

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 14:56:40**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:28:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered 'once (ONCE)'	(b) (4) Riley King (b) (4) (b) (4)	16 Mar 2021 19:17:41

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:56:40

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:28:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered empty.	Riley King (b) (4)	16 Mar 2021 19:17:41

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 14:56:40**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:28:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered 'Other (OTHER)'	Riley King (b) (4)	16 Mar 2021 19:17:41

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:56:40

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:28:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered 'epidural'	(b) (4) Riley King (b) (4) (b) (4)	16 Mar 2021 19:17:41

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:28:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered '1 Nov 2020'	Riley King (b) (4)	16 Mar 2021 19:17:41

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:28:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered '0'	Riley King (b) (4)	16 Mar 2021 19:17:41

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 14:56:40**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:28:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	16 Mar 2021 19:17:41
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 14:56:40**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:28:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered '1 Nov 2020'	Riley King (b) (4)	16 Mar 2021 19:17:41

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 14:56:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:28:10
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
User entered 'No (N)'	Riley King (b) (4)	16 Mar 2021 19:17:41
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 14:56:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:28:10
User entered empty.	System	16 Mar 2021 19:17:41

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:28:10
User entered empty.	System	16 Mar 2021 19:17:41

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:28:10
User entered empty.	System	16 Mar 2021 19:17:41

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:56:40

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:19:50
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 07:28:25
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 07:28:25
	(b) (4)	
Data point term sent to Coder	System	06 Apr 2021 16:28:43
User entered 'B12 vitamin'	Sherry Henning (b) (4)	06 Apr 2021 16:28:24
	(b) (4)	

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:56:40

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:19:50
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	06 Apr 2021 16:28:24
	(b) (4)	

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:56:40

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:19:50
	(b) (4)	
User entered 'low back pain'	Sherry Henning (b) (4)	06 Apr 2021 16:28:24
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 14:56:40**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:19:50
	(b) (4)	
User entered '500'	Sherry Henning (b) (4)	06 Apr 2021 16:28:24
	(b) (4)	

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:56:40

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:19:50
	(b) (4)	
User entered 'ug (ug)'	Sherry Henning (b) (4)	06 Apr 2021 16:28:24
	(b) (4)	

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:56:40

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:19:50
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	06 Apr 2021 16:28:24
	(b) (4)	

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:56:40

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:19:50
	(b) (4)	
User entered 'twice daily (BID)'	Sherry Henning (b) (4)	06 Apr 2021 16:28:24
	(b) (4)	

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:56:40

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:19:50
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	06 Apr 2021 16:28:24
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 14:56:40**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:19:50
	(b) (4)	
User entered 'Oral (ORAL)'	Sherry Henning (b) (4)	06 Apr 2021 16:28:24
	(b) (4)	

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:56:40

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:19:50
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	06 Apr 2021 16:28:24
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:19:50
	(b) (4)	
User entered '27 Mar 2021'	Sherry Henning (b) (4)	06 Apr 2021 16:28:24
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 14:56:40**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:19:50
	(b) (4)	
User entered '0'	Sherry Henning (b) (4)	06 Apr 2021 16:28:24
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 14:56:40**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:19:50
	(b) (4)	
User entered 'Yes (Y)'	Sherry Henning (b) (4)	06 Apr 2021 16:28:24
	(b) (4)	

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:56:40

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:19:50
	(b) (4)	
User entered empty.	Sherry Henning (b) (4)	06 Apr 2021 16:28:24
	(b) (4)	

US3062048

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 14:56:40

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Glover (b) (4)	09 Apr 2021 13:19:50
	(b) (4)	
User entered 'No (N)'	Sherry Henning (b) (4)	06 Apr 2021 16:28:24
	(b) (4)	

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 14:56:40**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Apr 2021 16:28:24

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Apr 2021 16:28:24

**US3062048**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 14:56:40**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Apr 2021 16:28:24

US3062048

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:56:40

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:16:34
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
User closed query 'Please add to procedure tab (noted in CM)' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 20:51:52
Query 'Please add to procedure tab (noted in CM)' answered with 'Added ' (Site from CRA).	Riley King (b) (4)	18 Mar 2021 20:35:24
	(b) (4)	
User opened query 'Please add to procedure tab (noted in CM)' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 17:26:51
	(b) (4), (b) (6)	
User closed query 'please add epidural steroid injection' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 17:26:51
	(b) (4), (b) (6)	
Query 'please add epidural steroid injection' answered with 'It has been added ' (Site from CRA).	Riley King (b) (4)	18 Mar 2021 14:56:35
	(b) (4)	
User opened query 'please add epidural steroid injection' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 20:21:08
	(b) (4), (b) (6)	
User closed query 'please verify epidural steroid injection in November 2020 per hosp record' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 20:21:08
	(b) (4), (b) (6)	
Query 'please verify epidural steroid injection in November 2020 per hosp record' answered with 'Reconciled ' (Site from CRA).	Riley King (b) (4)	16 Mar 2021 19:18:07
	(b) (4)	
User opened query 'please verify epidural steroid injection in November 2020 per hosp record' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 20:43:33
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:38:47
	(b) (4), (b) (6)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Cayla Lawless (b) (4)	14 Jan 2021 21:20:45
	(b) (4)	
User entered 'No (N)'	marissa Mueller (b) (4)	01 Sep 2020 19:45:37
	(b) (4)	

US3062048

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:56:40

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:40:42
User entered '11 Jan 2021'	Cayla Lawless (b) (4)	16 Feb 2021 18:07:41
	(b) (4)	

US3062048

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:56:40

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:40:41
User entered 'Excision of L5-S1 facet synovial cyst'	Cayla Lawless (b) (4)	16 Feb 2021 18:07:41
	(b) (4)	

US3062048

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:56:40

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:40:44
User entered 'Adverse Event (AE)'	Cayla Lawless (b) (4)	16 Feb 2021 18:07:41
	(b) (4)	

US3062048

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:56:40

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:40:46
User entered empty.	Cayla Lawless (b) (4)	16 Feb 2021 18:07:41
	(b) (4)	

US3062048

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:56:40

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:18:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4)	01 Mar 2021 20:40:25
User entered '11 Jan 2021'	Cayla Lawless (b) (4)	16 Feb 2021 18:09:00
	(b) (4)	

**US3062048**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 09 Jun 2021 14:56:40**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:18:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:40:26
User entered 'Left L5-S1 hemilaminotomy decompression with partial facetectomy'	Cayla Lawless (b) (4) (b) (4)	16 Feb 2021 18:09:00

**US3062048**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 09 Jun 2021 14:56:40**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:18:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:40:30
User entered 'Adverse Event (AE)'	Cayla Lawless (b) (4) (b) (4)	16 Feb 2021 18:09:00

US3062048

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:56:40

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:18:29
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:40:33
User entered empty.	Cayla Lawless (b) (4) (b) (4)	16 Feb 2021 18:09:00

US3062048

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:56:40

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:18:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 20:40:11
User closed query 'Per CDM: Thank you for adding Con Proc #4 and 5 in response to DM CLR query on AE#1. Please note that the dates of MRI and X-RAY (11 Feb 2021) are after the stop date of the corresponding AE #1 and per AE narrative these were performed prior to surgery. Please review and verify the dates of Con Proc #4 and #5.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 09:31:20
Query 'Per CDM: Thank you for adding Con Proc #4 and 5 in response to DM CLR query on AE#1. Please note that the dates of MRI and X-RAY (11 Feb 2021) are after the stop date of the corresponding AE #1 and per AE narrative these were performed prior to surgery. Please review and verify the dates of Con Proc #4 and #5.' answered with 'reconciled ' (Site from DM).	Riley King (b) (4) (b) (4)	27 Feb 2021 21:41:06
User entered '11 Jan 2021' reason for change: Per Query Resolution	Riley King (b) (4) (b) (4)	27 Feb 2021 21:40:58
User opened query 'Per CDM: Thank you for adding Con Proc #4 and 5 in response to DM CLR query on AE#1. Please note that the dates of MRI and X-RAY (11 Feb 2021) are after the stop date of the corresponding AE #1 and per AE narrative these were performed prior to surgery. Please review and verify the dates of Con Proc #4 and #5.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 15:02:40
User entered '11 Feb 2021'	Riley King (b) (4) (b) (4)	24 Feb 2021 16:54:41

US3062048

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:56:40

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:18:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 20:40:13
User entered 'MRI'	Riley King (b) (4)	24 Feb 2021 16:54:41

**US3062048**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 09 Jun 2021 14:56:40**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:18:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4)	01 Mar 2021 20:40:15
User entered 'Adverse Event (AE)'	Riley King (b) (4)	24 Feb 2021 16:54:41

US3062048

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 14:56:40

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:18:33
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4)	01 Mar 2021 20:40:17
User entered empty.	Riley King (b) (4)	24 Feb 2021 16:54:41

US3062048

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:56:40

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:18:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:51:34
User closed query 'Per CDM: Thank you for adding Con Proc # 5 in response to DM CLR query on AE#1. Please note that the date of X-RAY (11 Feb 2021) is after the stop date of the corresponding AE #1 and per AE narrative the procedure was performed prior to surgery. Please review and verify the date of this Con Proc.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 10:39:23
Query 'Per CDM: Thank you for adding Con Proc # 5 Riley King in response to DM CLR query on AE#1. Please note that the date of X-RAY (11 Feb 2021) is after the stop date of the corresponding AE #1 and per AE narrative the procedure was performed prior to surgery. Please review and verify the date of this Con Proc.' answered with 'reconciled ' (Site from DM).	Riley King (b) (4) (b) (4)	16 Mar 2021 19:03:35
User entered '11 Jan 2021' reason for change: Data Entry Error	Riley King (b) (4) (b) (4)	16 Mar 2021 19:03:25
User opened query 'Per CDM: Thank you for adding Con Proc # 5 in response to DM CLR query on AE#1. Please note that the date of X-RAY (11 Feb 2021) is after the stop date of the corresponding AE #1 and per AE narrative the procedure was performed prior to surgery. Please review and verify the date of this Con Proc.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 09:32:29
User entered '11 Feb 2021'	Riley King (b) (4) (b) (4)	24 Feb 2021 16:54:58

US3062048

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:56:40

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:18:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4)	29 Mar 2021 20:51:34
User entered 'X-ray'	Riley King (b) (4)	24 Feb 2021 16:54:58

US3062048

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 14:56:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:18:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4)	29 Mar 2021 20:51:34
User entered 'Adverse Event (AE)'	Riley King (b) (4)	24 Feb 2021 16:54:58

**US3062048**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (5)**

**Generated On: 09 Jun 2021 14:56:40**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:18:35
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:51:34
User entered empty.	Riley King (b) (4) (b) (4)	24 Feb 2021 16:54:58

US3062048

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 14:56:40

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:18:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4), (b) (6)	29 Mar 2021 20:51:34
User entered '11 Nov 2020'	Riley King (b) (4)	18 Mar 2021 20:35:14

US3062048

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 14:56:40

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:18:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4)	29 Mar 2021 20:51:34
User entered 'Lumbar epidural'	Riley King (b) (4)	18 Mar 2021 20:35:14

US3062048

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 14:56:40

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:18:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:51:34
User entered 'Medical History (MH)'	Riley King (b) (4) (b) (4)	18 Mar 2021 20:35:14

**US3062048**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (7)**

**Generated On: 09 Jun 2021 14:56:40**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:18:39
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:51:34
User entered empty.	Riley King (b) (4) (b) (4)	18 Mar 2021 20:35:14

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'USA-US090-2021-MRNA-1273-P301000002'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'Yes (Y)'	System	15 Jan 2021 13:34:47

US3062048

Folder: SAE USA-US090-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:40

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'No (N)'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'No (N)'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'Yes (Y)'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'No (N)'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'No (N)'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'No (N)'	System	15 Jan 2021 13:34:47

US3062048

Folder: SAE USA-US090-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'Richard'	System	15 Jan 2021 13:34:47

US3062048

Folder: SAE USA-US090-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'Glover'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered '700 Medical Center Dr.'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'Newton'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'KS'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered '67114'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4)	21 Jan 2021 17:08:52
User entered 'US'	System	15 Jan 2021 13:35:40

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Feb 2021 16:56:02
User entered '2'	System	21 Jan 2021 17:08:42
User entered '1'	System	15 Jan 2021 13:35:40

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'USA-US090-2021-MRNA-1273-P301000002'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'Yes (Y)'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'No (N)'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'No (N)'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'Yes (Y)'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'No (N)'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'No (N)'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'No (N)'	System	15 Jan 2021 13:34:47

US3062048

Folder: SAE USA-US090-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'Richard'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'Glover'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered '700 Medical Center Dr.'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'Newton'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'KS'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered '67114'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 17:08:52
User entered 'US'	System	15 Jan 2021 13:35:40

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Feb 2021 16:56:02
User entered '2'	System	21 Jan 2021 17:08:42
User entered '1'	System	15 Jan 2021 13:35:40

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 14:56:40**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered '15/Jan/2021 13:35'	(b) (4) System	15 Jan 2021 13:35:40

US3062048

Folder: SAE USA-US090-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:56:40

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 17:08:52
User entered 'I'	(b) (4), (b) (6)	15 Jan 2021 13:35:40

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'USA-US090-2021-MRNA-1273-P301000002'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'Yes (Y)'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'No (N)'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'No (N)'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'Yes (Y)'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'No (N)'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'No (N)'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'No (N)'	System	15 Jan 2021 13:34:47

US3062048

Folder: SAE USA-US090-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'Richard'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'Glover'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered '700 Medical Center Dr.'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'Newton'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'KS'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered '67114'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 17:08:52
User entered 'US'	System	15 Jan 2021 13:35:40

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Feb 2021 16:56:02
User entered '2'	System	21 Jan 2021 17:08:42
User entered '1'	System	15 Jan 2021 13:35:40

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 14:56:40**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered '21/Jan/2021 12:08'	(b) (4) System	21 Jan 2021 17:08:42

US3062048

Folder: SAE USA-US090-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:56:40

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:08:52
User entered 'I'		21 Jan 2021 17:08:42

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'USA-US090-2021-MRNA-1273-P301000002'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'Yes (Y)'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'No (N)'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'No (N)'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'Yes (Y)'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'No (N)'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'No (N)'	System	15 Jan 2021 13:34:47

US3062048

Folder: SAE USA-US090-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:40

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'No (N)'	System	15 Jan 2021 13:34:47

US3062048

Folder: SAE USA-US090-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:40

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'Richard'	System	15 Jan 2021 13:34:47

US3062048

Folder: SAE USA-US090-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 14:56:40

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'Glover'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered '700 Medical Center Dr.'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'Newton'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered 'KS'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4), (b) (6)	15 Jan 2021 13:35:32
User entered '67114'	System	15 Jan 2021 13:34:47

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:08:52
User entered 'US'	System	15 Jan 2021 13:35:40

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 14:56:40**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	16 Feb 2021 16:56:02
User entered '2'	System	21 Jan 2021 17:08:42
User entered '1'	System	15 Jan 2021 13:35:40

**US3062048**

**Folder: SAE USA-US090-2021-MRNA-1273-P301000002**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 14:56:40**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
	(b) (4)	
User entered '16/Feb/2021 10:56'	System	16 Feb 2021 16:56:02

US3062048

Folder: SAE USA-US090-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:56:40

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 17:38:25
User signature succeeded.	Troy Holdeman (b) (4)	02 Apr 2021 20:20:55
User entered 'I'	(b) (4) (b) (4), (b) (6)	16 Feb 2021 16:56:02